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ABSTRACT

Proceedings are presented from a meeting designed to encourage and assist university-based researchers and public policy-makers in the formation of meaningful, long-term collaborations that would ultimately increase chances of competing successfully for research grants on the efficacy of services and systems of care for children and adolescents with serious emotional disturbances. The proceedings emphasize the use of experimental design. Summarized presentations are offered in the following areas: "Relating Child and Adolescent Service System Program Goals to a Research Design"; "Issues in Resarch Design"; "Sampling Issues"; "Measures/Outcomes--System Outcomes"; "Measures/Outcomes--Client Outcomes"; and "Institutional Review Boards." Appendices, which comprise over half the document, include: (1) "Research on Service Delivery and Systems of Care: Recommendations for the NIMH Child Mental Health Research Plan"; (2) "Issues in Research Design" by Michael Hendricks; (3) "Vermont System for Tracking Client Progress"; (4) "Some Possible Measures for Improvements to the CASSP System and Service Delivery" by Michael Hendricks; (5) federal regulations on protection of human subjects; and (6) a list of four technical assistance resources. (19 references) (PB)

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Child and Adolescent Service System Program Technical Assistance Research Meeting

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Summary of Proceedings

CASSP Technical Assistance Center
Georgetown University Child Development Center

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CHILD AND ADOLESCENT SERVICE SYSTEM PROGRAM
TECHNICAL ASSISTANCE RESEARCH MEETING

MAY 1 - 2, 1990

SUMMARY OF PROCEEDINGS

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APPENDIX A: Research on Service Delivery and Systems of Care: Recommendations for the NIMH Child Mental Health Research Plan

APPENDIX B: Issues in Research Design

APPENDIX C: Vermont System for Tracking Client Progress

APPENDIX D: Some Possible Measures of Improvements to the CASSP System and Service Delivery

APPENDIX E: Protection of Human Subjects

APPENDIX F: Technical Assistance Resources

PREFACE

During the past decade significant progress has been made in the area of child and adolescent mental health services. In 1982 Jane Knitzer documented the failure of our service delivery systems to provide both adequate and appropriate care to the increasing numbers of children with or at risk of developing serious emotional disturbances in this country. Following this publication and the subsequent formation of the Child and Adolescent Service System Program (CASSP) of the National Institute of Mental Health (NIMH), there has been a steady growth in the development of children's mental health services and increased utilization of the comprehensive, community-based "system of care" model as an alternative to traditional service approaches. Along with these changes, there has been increased attention on local, state and federal levels to legislative changes that would mandate the provision of comprehensive and coordinated services to children and adolescents. The formation of a strong and growing network of parent support groups and statewide and national parent organizations is yet another indication of the dramatic and positive advances that have ensued.

Only during the past few years, however, has the need for accelerating and expanding the research base regarding the etiology, diagnosis and treatment of child and adolescent mental disorders as well as regarding the establishment and maintenance of effective service delivery systems become a major focus for the NIMH. This concern has culminated in the recent development of a National Plan for Research on Child and Adolescent Mental Disorders which was built upon the 1989 report of the Institute of Medicine of the National Academy of Sciences. Included in this plan are specific recommendations on service delivery and system of care research as well as suggestions on ways to eliminate impediments to research such as the lack of human and financial resources needed to adequately stimulate the field.

On May 1 - 2, 1990, CASSP sponsored a technical assistance meeting devoted to research issues which was held in Washington, D.C. The purpose of the CASSP Technical Assistance Research Meeting was to encourage and assist the field, made up largely of university-based researchers and public policymakers, in the formation of meaningful, long-term collaborations that would ultimately increase their chances of successfully competing for research demonstration grant awards (R18s) -- that is, research on the efficacy of innovative services and systems of care which have been developed largely as a result of CASSP goals. Such research requires an understanding of the pertinent theoretical, design, and measurement issues that will most likely produce the generalizable knowledge needed to advance the field.

Although the use of experimental design has been particularly emphasized in these proceedings, it is certainly not the only means of producing important new scientific information. In fact, a number of factors may create the necessity for the use of other designs. One such factor is the degree to which a problem or issue has received previous study, forming a foundation of knowledge upon which to base hypotheses or research questions. Descriptive research approaches may be needed for service strategies or problem areas which have received little prior study. Further, many of the technologies for conducting research on service delivery and systems of care for children and youth are in need of further refinement. Thus, the need for developmental research is also critical. Information about a variety of research designs and, perhaps, the need to develop new methods and measures for studying mental health services for children, adolescents, and their families will be addressed in greater depth in future NIMH activities.

The Child and Family Support Branch and its technical assistance and research and training centers together with other Division of Applied and Services Research staff are available for continuing consultation and assistance in proposal development as well as training and other career development needs.

Diane L. Sondheimer, Ph.D.
Chief, Research Demonstration Program
Child and Family Support Branch
Division of Applied and Services Research
National Institute of Mental Health

INTRODUCTION

Ms. Jean Athey, Project Officer
Child and Adolescent Service System Program
National Institute of Mental Health

Ms. Athey indicated that the National Institute of Mental Health (NIMH) is concerned about insuring that the goals of the Child and Adolescent Service System Program (CASSP) are met within a research framework. The CASSP grant announcements offer funds for research demonstration projects, and NIMH seeks to assist states in preparing the strongest possible applications. Thus, the goal of this meeting was to focus on research design, data analysis, instrumentation, and other related issues in order to assist potential applications to respond to the CASSP research announcements.

Ira Lourie, M.D., Chief
Child and Family Support Branch
National Institute of Mental Health

Dr. Lourie indicated that CASSP has been operating for five years. When the program started, there was very little state planning and commitment in the area of children's mental health services. The premise of CASSP was to provide financial and technical assistance to states to assist them in creating improved systems of care for children and their families. He reported that some systems have now been developed, in some cases in very innovative and creative ways, and that there is now an opportunity to begin to ask some serious questions about the efficacy of these systems and about the system development process. In the past, we were unable to study systems that did not yet exist; however, at this point in the movement there are some systems which can be studied. Dr. Lourie stated that CASSP is now moving into a new research phase to take advantage of this opportunity. The goal of NIMH is to create a knowledge base from which greater system building efforts can proceed.

Dr. Lourie described the 1990 CASSP grant announcements and elaborated on several key aspects. He defined a research demonstration as taking the state CASSP process and applying it to the local level within a research framework. "We have to ask questions and aid our process in a way that those questions can be answered in a reasonable way." One of the 1990 research demonstration priorities is for research on "innovative service system development and functioning." This concept rests on the notion that there are systems of care being developed through CASSP, the Robert Wood Johnson program, the Casey Foundation initiative, and by individual states. These system building efforts are well funded, and they should be generating questions. The CASSP announcement offers the opportunity to receive research funds to address some of these questions.

A second 1990 priority is comprehensive service research for homeless adolescents who have or are at risk for severe emotional disturbance. This provides an opportunity for those working with this population to develop systems and to study how the systems work and their effects on the health, mental health, and social welfare of homeless adolescents.

Dr. Lourie closed by noting that this conference was intended to be an opportunity to explore the research issues and how to design research projects in response to the CASSP announcements.

RELATING CASSP GOALS TO A RESEARCH DESIGN

Robert Friedman, Ph.D., Director
Research and Training Center for Children's Mental Health
Florida Mental Health Institute
University of South Florida

Dr. Friedman provided a context for the CASSP announcements by discussing "where we are in the field" and some of the issues that are confronting those who are attempting to improve services for children and adolescents with serious emotional disorders and their families. He reported that a study of key informants was completed several months ago in order to obtain their perspectives, as CASSP turned five years old, on what has been accomplished. There appeared to be widespread consensus that, in its five years, CASSP has had enormous success in a number of areas, including:

- Increasing the attention and recognition of the needs of children and adolescents across the country.

- Strengthening leadership at the state level in the children's mental health area.

- Creating a network of information exchange and support amongst people in different states.

- Creating a vision of what a system of care should be, based on the best available research data and emphasizing the need for systems to be community-based and comprehensive, to use individualized approaches to treatment, to have a strong family focus and to involve families in all aspects of service delivery, and to be sensitive to the needs of culturally diverse groups and to be culturally competent.

- Generating significant new resources for children's mental health in many states.

Dr. Friedman also noted that legislation is pending at the Federal level which would provide funds to help states build and strengthen their systems of care. He emphasized that it does not do a lot of good to study systems unless you have systems at a state of operation that can be effective. The Children's Community Mental Health Services Improvement Act of 1990, if funded, would be a very significant effort in this direction.

Despite a lot of progress, Dr. Friedman acknowledged that there is a long way to go in operationalizing our vision and values. "And there are large discrepancies between what the state of knowledge is and what we are actually doing out there, the numbers of children and families that need help and the numbers who are actually receiving help, and what we emphasize in terms of family involvement and cultural competence in relation to what is actually being done around the country. We have a long way to go . . . And if we are to continue to move the agenda that we have for children and adolescents ahead, it is important that we increase the base of support for our goals, the CASSP goals, for children and families." Dr. Friedman stated that in order to move this agenda ahead, it will be necessary to tackle more difficult and complex issues, to put our assumptions and beliefs to stringent tests, and to sharpen our thinking about the linkages between our activities and the outcomes that we seek to achieve as well as to consider other approaches to achieving these outcomes. Further, we need to gather more compelling data and research evidence with which we can reach out to policymakers and to our own professional colleagues so that we don't remain "a small club," one with strongly held beliefs but which remains a very silent part of the field. In addition, we need to be continually open to learning better ways of doing things. In this context, the CASSP research demonstration announcements provide an exciting opportunity.

Dr. Friedman also recognized that increased research is needed as more and more states and communities become involved in system improvement efforts. "I'm sure you've had this experience in your state. The question is asked, 'Do we know enough about what works to justify supporting more services in the communities? Is there a sufficient empirical base? Is there a sufficient research base for us to go ahead and invest significant resources in systems of care?' And I think that, as money is tighter and tighter, those questions are going to be asked more and more, and it's going to become harder to convince people unless we get the kind of research evidence that I think we all acknowledge is needed."

Dr. Friedman identified a series of critical needs for research. He first suggested that the interventions implemented and studied must be **meaningful and important** in terms of CASSP goals and system outcomes. Potential research issues include:

- **Research on Alternatives to Residential Treatment** - This may involve exploring alternatives to out-of-state placement or out-of-county placement. In many states, at least two-thirds of the budgets are going to out-of-home placements, and there is no research base to support the efficacy of these types of services. As long as systems continue to be out of balance, the resources are not likely to be available to develop community-based services. States have implemented a number of strategies to reduce out-of-home placement including: providing new services, developing individualized treatment approaches, changing the structure of the service system, changing the responsibilities of different agencies, changing the responsibilities of the local level in relation to the state level, changing reimbursement systems, creating more flexible pots of money to allow treatment to be more individualized, creating new structures that change the decision-making or the gatekeeping process by which youngsters are removed from their homes and placed in out-of-home placements, improving the data collection system within a state, and providing more accountability at the local level. Training is another strategy that states have used in an attempt to reduce out-of-home placements. Some have focused their efforts specifically on youngsters who already are out-of-home or who are at high risk of out-of-home placement. In this area, Dr. Friedman stressed that it is important to look not only at system outcomes (such as broad numbers of youngsters who are placed and length of stay) but also to combine this with individual child and family outcomes including clinical measures and measures of functioning.

- **Research on Innovative Services** - Many innovative services have developed, particularly in the 1980s. These include individualized treatment approaches, case management with wraparound services, mobile crisis services, intensive home-based services, respite care, parent support, therapeutic foster care, and day treatment. While our focus on community-based systems is essential, we also need to remember that some of the components of the system of care have not yet been adequately studied, and it is reasonable to develop research demonstrations that look at some of the critical components within the system.

- **Research on Reimbursement and Funding Strategies** - This area involves creating and studying fiscal incentives for home and community-based services. Some of the Medicaid changes offer compelling opportunities for states, the new EPSDT regulations, for example. Many states are moving toward creating flexible pots of money, but there has been no research on the effectiveness of flexible funding. Support for this concept could be generated much more rapidly if there were good research. Additionally, though it may be beyond us, research is needed on different reimbursement mechanisms.

- **Research on Involving and Supporting Families** - This has been a critical focus of CASSP since its earliest phase and there are many related research opportunities. For example,

people consistently recognize the need to involve families in treatment planning, but there are few people who feel comfortable about the strategies they have developed to achieve this, and there has been little evaluation. Research is needed to compare different strategies or to evaluate strategies from the family perspective, as well as from the treatment plan perspective, to determine the outcomes of involving parents in different ways. We invest considerable time and money in training parents and professionals to understand each other's roles and to produce closer partnerships between them, and there are many research possibilities around such training as well as around parent support groups and different strategies for developing them. It also is important to look at the relationship of involvement of parents to satisfaction, and the relationship of both involvement and satisfaction to outcomes for the child and family.

- **Research on Multi-Agency Collaborations** - This also has been a part of the CASSP philosophy from the beginning. One of the things that all CASSP states have done is to develop some type of interagency entity, cluster, case review team, or planning structure. How do we do this effectively? What are the outcomes? Do they, in fact, produce different types of treatment plans? Do they, in fact, produce more joint funding or sharing of information between agencies? Different kinds of services? Dr. Friedman suggested that this is an area in which we have accepted that this is desirable without putting it to the test. There are strategies emerging for measurement of interorganizational relationships which may be useful in looking at interagency communication networks, resource sharing, and other aspects of interagency collaboration.

- **Research on Developing Culturally Competent Systems of Care** - A key goal of CASSP is recognizing the increasing cultural diversity of our country and ensuring that services are responsive to the needs of individuals of varying cultural and ethnic backgrounds. Research is needed to look at the efficacy of different service approaches for different groups, approaches to identifying those in need within different groups, the effectiveness of different strategies for changing professional actions and attitudes, and the effectiveness of changes in policies. Studies are needed to determine how we go about operationalizing and implementing the value of cultural competence and determining which strategies achieve the best outcomes.

- **Research on Assessment of Treatment Planning and Clinical Decision Making** - The heart of what we are trying to do with children and families is to develop treatment plans that are individualized. Yet, we have done very little research within our systems on the assessment and treatment planning process. What are the effects of different approaches to information gathering? For example, what are the effects of approaches that are more ecological in focus and approaches that are more focused on the strengths of youngsters and families and on their cultural heritage? Do these approaches result in different treatment plans? In better treatment plans? In better outcomes? In addition, little research has been done on the group treatment planning process -- the organization of groups, the structure, membership, and process by which they operate. It may be useful to look at the mechanisms we use for developing treatment plans and whether they, in fact, result in more creative processes.

- **Research on Cost of Care** - This area includes the issue of cost of care and cost of noncare as well as who bears the cost (public system, private system, or parents). It is going to be necessary to do a far better job of clearly documenting the cost of care. Two of the projects which have had the greatest impact in the country are the Ventura County Children's Mental Health Demonstration Project and the Alaska Youth Initiative. If you ask the people who designed and managed those projects, they will tell you that the impact of their projects can be attributed in part to the measurement of outcomes and the systematic gathering of data, including data on cost.

In closing, Dr. Friedman reemphasized the importance of focusing on interventions that are meaningful to the system in terms of the goals of CASSP and of the state and of relating the intervention to those goals conceptually. Interventions must be powerful enough to have some effect in achieving the goals and must be embedded in a design that will yield a clear interpretation of the findings so that we can have some generalizable conclusions that will allow the entire children's mental health field to move ahead. For additional discussion of research needs, see "Research on Service Delivery and Systems of Care: Recommentaions for the NIMH Child Mental Health Research Plan," included as Appendix A.

Len Bickman, Ph.D., Director
Center for Mental Health Policy
Vanderbilt University

Dr. Bickman discussed the grant review process and some of the problems identified in previous applications. He first described the Initial Review Group (IRG) that is organized by an Executive Secretary who is independent of the CASSP program office. This reflects a strong attempt by the government to separate funding decisions from the program offices. Program staff are not permitted to address the review group unless the Executive Secretary allows this. Currently, there is no standing review committee in the children's area, and so each year the group is reconstituted. While some people may serve again, others may not, making it hard to predict the culture that may develop during the review, the criteria the committee will think are important, or the projects they think should be funded. A primary reviewer is assigned to each proposal, and this person has a great deal of influence on how the proposal will be evaluated and voted on. The entire committee discusses the proposal, with some emphasis on the strong points but primarily focusing on the weak points. The committee makes a decision about whether or not to approve the proposal. For those that are approved, each committee member assigns a priority score ranging from 100 to 500. An overall priority score is derived -- the lower the number, the better the score. A percentile score also is attached to each proposal that reflects the ranking of priority scores of all proposals reviewed by the committee.

Dr. Bickman then explained the criteria by which a proposal is likely to be assessed (See Demonstration Proposal Assessment on page 6). First, he discussed assessment of the intervention. Reviewers will attempt to evaluate the quality of the intervention, referred to as "program theory." What is the theory behind this intervention? Does it make sense? The program theory refers to the linking of the intervention and what it is intended to accomplish (its outcomes) and whether the connection makes sense either based upon previous research or based upon logic. Dr. Bickman noted that one of the problems identified in previous proposals was that the intervention was presented in the proposal with no justification. "You have to be able to put the intervention into the context that makes it compelling as to why this intervention should be tested. One of the major departures you have to consider is that the review committee really doesn't care about whether these children in your state are getting these services or not. This grant announcement is not to fund services for children. It is to create knowledge about services for children."

The key, according to Dr. Bickman, is to create generalizable knowledge from your intervention. Those in other states must be able to replicate what is done. "If it's an intervention that is very idiosyncratic to one situation, my sense is that's not going to be a very appealing intervention. It has to be something that other people have the opportunity to apply, because the purpose of the NIMH in the 1990s is to create knowledge, not to provide funds to states to provide services."

DEMONSTRATION PROPOSAL ASSESSMENT

INTERVENTION

A. PROGRAM THEORY

1. Problem
2. Intervention

B. IMPLEMENTATION - FEASIBILITY

1. Organizational
2. Financial
3. Human

EVALUATION

A. DESIGN AND MEASUREMENT

1. Internal Validity
2. Statistical Validity
3. External Validity
4. Construct Validity

B. IMPLEMENTATION - FEASIBILITY

1. Organizational
2. Financial
3. Human

Thus, the intervention has to be conceptually sound; the intervention must be related to the outcomes that are supposed to occur. Further, the intervention must be policy relevant, and reviewers will be looking for interventions that are likely to create large impacts. Basic researchers may be interested in very small effects that have little or no policy relevance, but produce meaningful theoretical gain. For research demonstrations, however, interventions with very small effects are not going to be as credible as something that can really change the nature and quality of services and outcomes for children.

The nature of the problem also must be discussed from a research perspective. Reviewers want to see an understanding of the context in which the demonstration will be applied. Previous data about the problem in the community or state gives an advantage in the proposal as well as a sense that prior work has been done. "The demonstration aspect is very critical. It has to be relevant and you have to show it's relevancy to solving a problem that you have. Which means you need to define the problem. Which means probably, any data that you have about the problem, is going to be advantageous in your proposal. Proposals that [only] seek to collect date to define the problem will not be very successful."

In sum, reviewers will look at the quality of the intervention -- Is the idea compelling? Is it important? Would it have an impact? Is it theoretically meaningful? Is it policy relevant? Is it exciting or innovative?

Committee members also will judge the applicant's ability to implement the intervention. States can hire the best proposal writers, but the capabilities of the organization to implement the intervention may be questionable. Proposals must demonstrate the organizational capability to put the intervention in place including needed connections, power, expertise, and resources. "What is it in this proposal that convinces me that this is a high probability event? Because I don't want them to spend the research dollars and the demonstration dollars on trying to demonstrate the futility of intervening in a system." There must be sense that change is possible and that the organization is capable of doing it. The proposal must contain sufficient funds to implement the intervention and must clearly indicate where additional funds needed to support the intervention will come from. Human resources also are critical. Does the director of the project have the experience and capability to run complex demonstration projects? The background of proposed personnel will demonstrate whether they have the needed experience and capability.

Dr. Bickman proceeded to discuss criteria for assessing the evaluation aspect of the proposal beginning with design and measurement issues:

- Internal Validity - Did the program cause the change? According to Dr. Bickman, some sort of comparison is going to be necessary to demonstrate that, in fact, the intervention was the one that did it.

- Statistical Validity - The design must be sufficiently sensitive to be able to detect an effect if it is present. This was the major downfall of previously submitted proposals--the sample sizes and the implementation of designs were too insensitive to detect effects. A reviewer can look at the design, the sample size, the type of instrumentation, and the type of analysis proposed and have a pretty good guess that even if the program is effective, the evaluation would not be sensitive enough to show that it was statistically significant. "All that this does is communicate to the larger field that these child interventions don't work, when in fact it was the evaluation that didn't work. And it's a critical element to be able to handle questions of statistical power and conclusion validity in your design."

- External Validity - This is a question of generalizability. If there is a very idiosyncratic program or very idiosyncratic population, the proposal probably has less of chance of being funded.

- Construct Validity - One aspect of construct validity relates to measurement or instrumentation. Does it measure what you say it is measuring? Is it valid and reliable? The construct also refers to the program itself. It is important to describe the intervention not only in operational terms but to raise it to a generalizable construct. "So, what do wraparound services do that should make it better for the child and family. If you only describe operationally what you're going to do without describing why it should be better, it's going to be less conceptual."

Dr. Bickman emphasized the importance of a good evaluation component in the proposal. "Essentially what the review team is doing is differentiating proposals -- how they differ, which ones are fundable, which ones are better than others . . . My sense is that the criteria for what is a good research design are clearer than for what is a good intervention. And the ability of a member of the committee to communicate those criteria to the rest of the committee is easier for research and evaluation criteria than it is for interventions . . . So discussion then falls more about what the evaluation looks like." Measurement issues, therefore, are very important.

Decisions will have to be made about how much money to put into the evaluation versus how much money is put into the intervention, and balance is an important concept. "Someone may say they want to provide this important intervention and it costs a lot of money to put it in, and they have to decide between having a control group or having a stronger intervention. These things, remember, go back to the basic purpose of these grants, which is not to provide services to children in your state, but to provide generalizable knowledge about what happens when you provide these services . . . So in terms of dollars, you have to be careful about how much money you put into services versus evaluation." Additionally, there is a sense that state generally can find service money somewhere else but cannot find research or evaluation dollars. This decision requires some hard choices; Dr. Bickman stated that his bias is to have the best evaluation design.

Dr. Bickman summarized important criteria for both the intervention and evaluation aspects of the project. The section of the proposal describing the intervention should demonstrate:

- Balance with the evaluation in terms of attention in the proposal and resources.

- Data-driven local description of the problem.

- Clear and conceptual description of the intervention.

- Ability to coordinate and manage the intervention.

- Sufficient resources for the intervention.

- High quality and experienced staff.

The component addressing the evaluation requires:

- Comparison groups (internal validity).

- Power analysis/statistical plan (statistical validity).

- Precise description of instruments (construct validity).
- Description of sampling of sites and clients (external validity).
- Ability to control design and sample (organizational resources).
- Sufficient funds for the evaluation (financial resources).
- High quality and experienced staff (human resources).

The proposal must show how random assignment will be done if that is proposed, where comparison groups will come from and that there will be cooperation from people who will be in comparison groups, evidence that you have access to the number of clients promised in the proposal, and so forth.

Proposed staff should include a team that is capable of implementing a complex field study which involves gaining access to clients, collecting data, and analyzing data, all within a short period of time. The best way to demonstrate this clearly is that proposed personnel have a track record in terms of successfully submitting other grant proposals, conducting studies, and publishing.

ISSUES IN RESEARCH DESIGN

Michael Hendricks, Ph.D., Consultant
MH Associates

Dr. Hendricks discussed the topic of research design. He reviewed six important questions related to research design (See "Issues in Research Design," Appendix B). The first three questions relate to the demonstration or intervention (What do I want to change?, How can I measure these changes?, and How can I intervene to produce changes?). The remaining three questions relate specifically to the research design (How can I detect any changes which do occur?, How can I be certain that my intervention caused these changes?, and How can I ensure that others can learn from my success?).

1. What do I want to change?

The first decision that this question requires is what the level of focus will be. Are you going to try to change things at the state level or at the local system level? Are you going to try to change service delivery or are you going to try to change client outcomes? This is an important decision which leads to identification of the "units of analysis." This simply means what it is that you are trying to affect. If you are trying to affect systems, then "systems" is what you want to analyze. You may be trying to affect families or children. The level of focus and units of analysis are two issues that are very much interrelated.

This question also requires a delineation of the specific problem to be addressed, the magnitude of the problem, and trends related to the problem. This is the "data driven local description" which makes the case that the project addresses a difficult issue.

2. How can I measure these changes?

This question addresses the evidence that you will be providing to show that you have made changes. Relevant issues for this question are validity, reliability, and sensitivity to change. Validity is simply that the measures you are using in fact measure what they are intended to measure. There are four ways to demonstrate that your measures are valid: they are consistent with common usage; they are consistent with alternative measures that others have used; they are internally consistent; and they predict future behavior.

Reliability also must be demonstrated, meaning that if you measured again next month, if there had been no change, you would get the same results. Composite measures almost always are better than separate measures as they are less unstable, and multiple measures are better than single measures. Additionally, uniform data collection techniques and instruments are necessary.

Sensitivity to change is another important measurement issue. You must have some room on your measures in order to have the opportunity for things to move and to show an effect. Having a range of possible responses is one approach, and continuous measures are better than categorical measures. In addition, it is necessary to guard against floor and ceiling effects, ensuring that the people you sample or the measures you use are not bumping up against the ends of scales so that there is no room to move and show a difference.

3. How can I intervene to produce changes?

This question addresses the intervention needed to produce changes and also to prove to others that you have made some changes. First, there must be a good concept in the intervention, a theoretical base. What exactly about your intervention is supposed to be

causing the effect? Several references listed in Appendix B, particularly Program Theory in Evaluation, may be helpful in this regard.

Regarding implementation of the intervention, it must be feasible. You must have the experience and the resources to do it, and not only that you can do it, but that other people can do it too if it turns out to be a good idea. The intervention must be monitored to ensure that it's being implemented, and proposals should indicate that you will monitor the intervention and will know if it is not being implemented well. Further, the intervention must be well documented so that if it does work, someone else will know what you did.

Finally, you want to have little "diffusion of treatment" or "leakage" or "contamination" between treatment and control groups or these groups will begin to look alike.

4. How can I detect any changes which do occur?

It is necessary not only to detect any changes which occur, but to demonstrate these changes to other people. This apparently was a major downfall of previous proposals. People were not able to show in their proposals that if there was an effect, they would able to show it in fact. The requirement here is to have the strongest statistical power you can possibly have. There are four considerations to maximize your statistical power:

- Increase sample size - While this is the first approach we think of, it is not always easy or even possible. There may only be so many counties in your state, and it may be too time consuming or expensive to add more families or children to your sample. While you may try to increase your sample size, there are other solutions as well. The book entitled How Many Subjects? Statistical Power Analysis in Research may be a helpful reference.

- Increase effect size - A second way that you can increase your statistical power is to have a larger effect or to be able to show the effect better. Strategies include ensuring that the intervention is strong and powerful, ensuring the integrity of the treatment, and ensuring that data collection is consistent and sensitive to maximum impact. Maximum impact means that if you have worked with families and you think that they are going to benefit most two months after you have worked with them, then measure them two months after you have worked with them. Don't measure them eight months after. Give yourself the best chance to show any effect that is there.

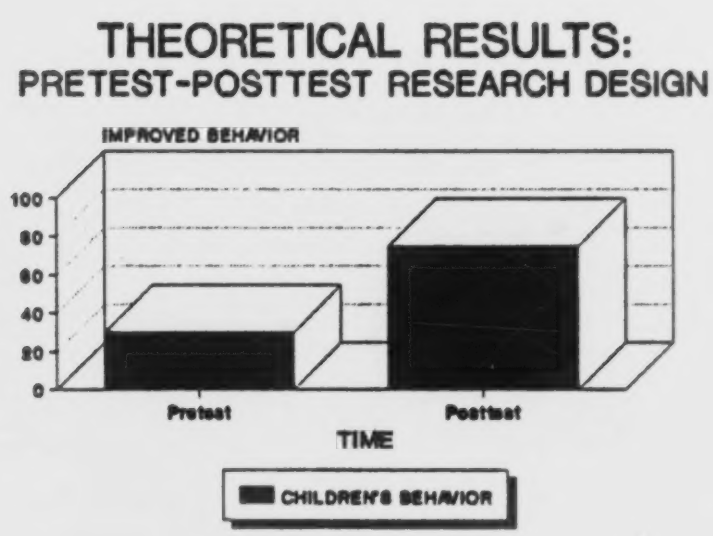
- Tests conducted - A third way you can increase your statistical power is by the kinds of statistical tests that you conduct since some are more powerful than others. For instance, parametric tests are almost always better than nonparametric tests. T-tests, analysis of variance, and multiple regression are almost always better than tests like chi squares, even though chi squares are what most of us do all the time. There are many better variations on chi squares. "Another consideration is that of reducing extraneous variation. In other words you want to clear away a lot of the underbrush, so if you've grown a flower you can actually see the flower. That's the way I think of this." One way of reducing extraneous variation is to learn as much as possible about factors which might influence peoples' progress such as gender, age, types of problems they are exhibiting, etc. These factors can be used as covariants, control variables in regression equations. This goes back to having a stratified sample.

- Alpha level - The fourth way to increase your statistical power is to change the alpha level, or the legendary $p < .05$. There is no magic to this confidence level or alpha level which specifies that 95 out of 100 times there's an effect and that 5 percent of the time you're going to be wrong. In public policy research, it would be acceptable if you were

right only 90 out of a 100 times or perhaps even less. You may be able to make a good case for changing the confidence or alpha level to .10 or .20.

5. **How can I be certain that my intervention caused these changes?**

The following graphic displays a common pretest-posttest design. It suggests that behavior improved dramatically from pretest to posttest and that the intervention was highly effective. However, the improvement may not have had anything to do with the intervention.



Other possible explanations include:

- o History - Other things may have been going on in between.
- o Maturation - The children may simply have gotten older and settled down.
- o Testing - Based on familiarity and experience with the test, the children may have performed better on the test the second time.
- o Instrumentation - There may have been a change in measuring instrument or perhaps caseworker observations were more sympathetic and positive the second time.
- o Regression to the Mean - This is a concept that if you select the most difficult cases to work with, even if the intervention is completely ineffective, the children will almost certainly look better on the posttest. The explanation is that you measured them specifically because they were very extreme scores, and statistically they almost have to come back towards more of an average score the second time around since it would be difficult for them to get worse.
- o Mortality - There may be children who drop out of the study, and it's possible that the most difficult youngsters dropped out leaving better children for the posttest.

It is critical to reduce threats to validity and to show in your proposals that you have reduced threats to validity to the lowest possible level. Pre-experimental designs (performance monitoring, pretest-posttest (one group), case studies, and cross-sectional surveys are the least desirable designs. Quasi-experimental designs are better designs and include non-equivalent control groups and longitudinal time series. With non-equivalent control group designs it is important to make the groups as equal as possible and to do something with one group and not with the other. The use of matching in the different groups can increase rigor. In the longitudinal time series designs, it is important to have a lot of data points, at least 30.

If it is possible to move up to a randomized experiment, this is the best design of all and is not as difficult to do as most people think. Pretest-posttest with two or more groups is a very common design, but a design that is equally as rigorous is a posttest only as long as there are two or more groups in random assignment.

6. How can I ensure that others learn from my success?

Can the results be generalized? Two aspects of this involve determining: 1) if results can be generalized beyond the study sample to your entire target population, and 2) if results can be generalized to other populations or to other states. This issue is addressed in the sampling plan. In the sampling plan, the populations you will be dealing with should be identified very clearly. Stratifying the sample in terms of children with very difficult problems or certain kinds of problems is beneficial, and random sampling is most desirable in terms of enhancing generalizability.

John Burchard, Ph.D., Professor
Department of Psychology
University of Vermont

Dr. Burchard described a particular kind of design called the time series analysis or repeated measures design. This design is being used in Vermont to evaluate services for severely emotionally disturbed children and adolescents. Dr. Burchard noted that his research environment is the State of Vermont and that an important part of that environment is the Vermont State Legislature. A major problem to legislators in Vermont and elsewhere is that we do not have outcome data on the children we serve. When Dr. Burchard was Commissioner of the State Child Protection Agency, legislators asked him many pointed questions: "Where are the severely emotionally disturbed children you served five years ago? How many have graduated from high school? How many have a job? How many are in the correctional system or the state mental hospital? You don't know! Why don't you know? I know where my cows are. I can tell you whether or not the services for my tractor are any good! Why can't you tell whether or not your services for kids are any good?" Dr. Burchard explained that when he left state government and went back to the university, he sought to build a collaborative process between the state and the university to determine what happens to the children we serve and what works best for what kind of children.

There is very little data available in Vermont (and in any state) on either clinical outcomes or on the level of restrictiveness of the environments in which children are served. The approach described by Dr. Burchard is in the developmental stages and is designed to collect data to determine if children are improving and if they are moving to more normalized environments.

Currently, there are 20 children on a system which tracks them on a daily basis. This information is converted graphically into weekly or monthly data. The categories of variables that are tracked include the adjustment of the child and the level of restrictiveness of the

child's environment. Measures that will monitor the services received and the satisfaction of the youth and parent will be implemented in the near future. For daily adjustment, a series of indicators of both positive and negative behaviors are recorded. These indicators include the following:

- o Physical aggression
- o Property damage
- o Theft
- o Runaway
- o Alcohol/drug abuse
- o Sexual acting out
- o Extreme verbal abuse
- o Sad
- o Anxious
- o Self-injury
- o Inappropriate bowel movements
- o Life threat
- o Sexual abuse/assault
- o Suicide attempt
- o Fire setting
- o Strange behavior
- o Cruelty to animals
- o Police contact
- o Self-confidence
- o Compliance
- o Peer interactions
- o School attendance
- o Vocational involvement

These 23 indicators comprise the Daily Adjustment Indicator Checklist shown on page 15 and 16. An assessment is made as to whether these primary indicators are changing over time. However, it is also important to look at the child's environment since an equally important goal is to move the child to the most normalized environment possible. Thus, in addition to adjustment indicators, the project is involved in tracking children along the following continuum of residential restrictiveness:

- o Independent living
- o Home
- o Relative/mentor
- o Foster home
- o Group home
- o Residential treatment center
- o Psychiatric hospital/corrections facility

The goal is to make the data collection system "provider friendly" by limiting the data collection task to five minutes per day and by providing periodic graphic feedback to the caretaker and the case manager. From a case management standpoint, the data can be analyzed on an individual basis, and each child can be used as his or her own control. THis approach also lends itself to a group design in which groups of youngsters receiving two different kinds of treatment might be tracked. For example, you could have two groups of 25 youngsters receiving two different types of care (e.g., therapeutic foster care versus group home care). The design would be more powerful if the children were randomly assigned to the two groups. Samples of graphs resulting from both individual and group designs are shown on pages 17 and 18.

Dr. Burchard emphasized that severely emotionally disturbed children receive many different placement changes and that many different services can be included in an intervention package. Therefore, he prefers going beyond the traditional pretest, posttest and follow-up data points and obtaining more frequent measures of adjustment. This approach is ongoing, proactive, looks at rates of change, and provides continuous follow-up over time. In a sense, the evaluation never stops. From the perspective of legislators and policymakers, more frequent outcome data is more user friendly. However, the approach is labor intensive and, therefore, may be more costly. The advantages and disadvantages of the approach are summarized on page 19.

DAILY ADJUSTMENT INDICATORS

ID# _____

Week beginning _____ (MONTH/DAY/YEAR)

Directions: *Please indicate according to your best judgement whether or not the following behaviors or events have occurred on this day. Fill in the appropriate circle.* (Y=YES, N=NO)

	M	T	W	T	F	S	S
1. **PHYSICAL AGGRESSION:** Did the child or youth hit, strike, bite, or scratch a person with intent to harm them? (Includes hitting with an object.)	Y N	Y N	Y N	Y N	Y N	Y N	Y N
2. **PROPERTY DAMAGE:** Did the child or youth damage property on purpose?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
3. **THEFT:** Did the child or youth take property without permission?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
4. **RUNAWAY:** Did the child or youth run away?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
5. **ALCOHOL/DRUG USE:** Did the child or youth use drugs or alcohol without permission?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
6. **SEXUAL ACTING OUT:** Did the child or youth engage in inappropriate sexual behavior which was displayed publicly or directed toward another person?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
7. **EXTREME VERBAL ABUSE:** Did the child or youth speak to another person in an extremely malicious, abusive or intimidating manner?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
8. **SAD:** Was the child or youth sad, withdrawn, or depressed to a degree which significantly interfered with participation in an important activity?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
9. **ANXIOUS:** Was the child or youth fearful, anxious, or worried to a degree which significantly interfered with participation in an important activity?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
10. **SELF-INJURY:** Did the child or youth harm or attempt to harm him or herself nonaccidentally?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
11. **INAPPROPRIATE BOWEL MOVEMENTS:** Did the child or youth intentionally smear his or her feces or deposit them in an inappropriate place?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
12. **LIFE THREAT:** Did the child or youth threaten or engage in physical assault in a manner which which you believe was life threatening?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
13. **SEXUAL ABUSE/ASSAULT:** Did the child or youth attempt to force him or herself upon another person sexually?	Y N	Y N	Y N	Y N	Y N	Y N	Y N

	M	T	W	T	F	S	S
14. **SUICIDE ATTEMPT:** Did the child or youth attempt to commit suicide?	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕
15. **FIRESETTING:** Did the child or youth set a fire without permission or set a fire in a manner which could have resulted in property damage or harm to others?	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕
16. **STRANGE BEHAVIOR:** Did the youth have delusions, hallucinations, obsessions, compulsions, or other bizarre behavior which significantly interfered with an important activity?	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕
17. **CRUELTY TO ANIMALS:** Did the child or youth torture, kill, or behave very cruelly toward any animal on purpose? (Does not include hunting with permission.)	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕
18. **SELF-CONFIDENCE:** Did the child or youth appear self-confident in his or her activities for more than 85% of the time?	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕
19. **COMPLIANCE:** Was the child's or youth's response to requests and general activity acceptable 85% of the time?	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕
20. **PEER INTERACTIONS:** Did the child or youth have good peer/sibling relations 85% of the time? (Please check ☐ if no peer or sibling contact on this day.)	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐
21. **SCHOOL ATTENDANCE:** As far as you know, did the child or youth receive credit for school attendance? (Please check ☐ if there was no school today.)	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐
22. **PARENT CONTACT:** Did the child or youth have contact with his or her natural or adoptive parent(s) on this day? (Includes letter, telephone call, or personal visit.)	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕
23. **VOCATIONAL INVOLVEMENT:** Did the child or youth work for pay (check "P") or as a volunteer (check "V")? (If the child or youth did not work check ☐)	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐	⊖ ⊕ ☐
24. **POLICE CONTACT:** Did the child or youth have contact with the police concerning his or her negative or suspicious behavior?	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕	⊖ ⊕

25. **POSITIVE:** What did the child or youth do today that was good?

Monday _____ **Friday** _____

Tuesday _____ **Saturday** _____

Wednesday _____ **Sunday** _____

Thursday _____

GENERAL COMMENTS: _____

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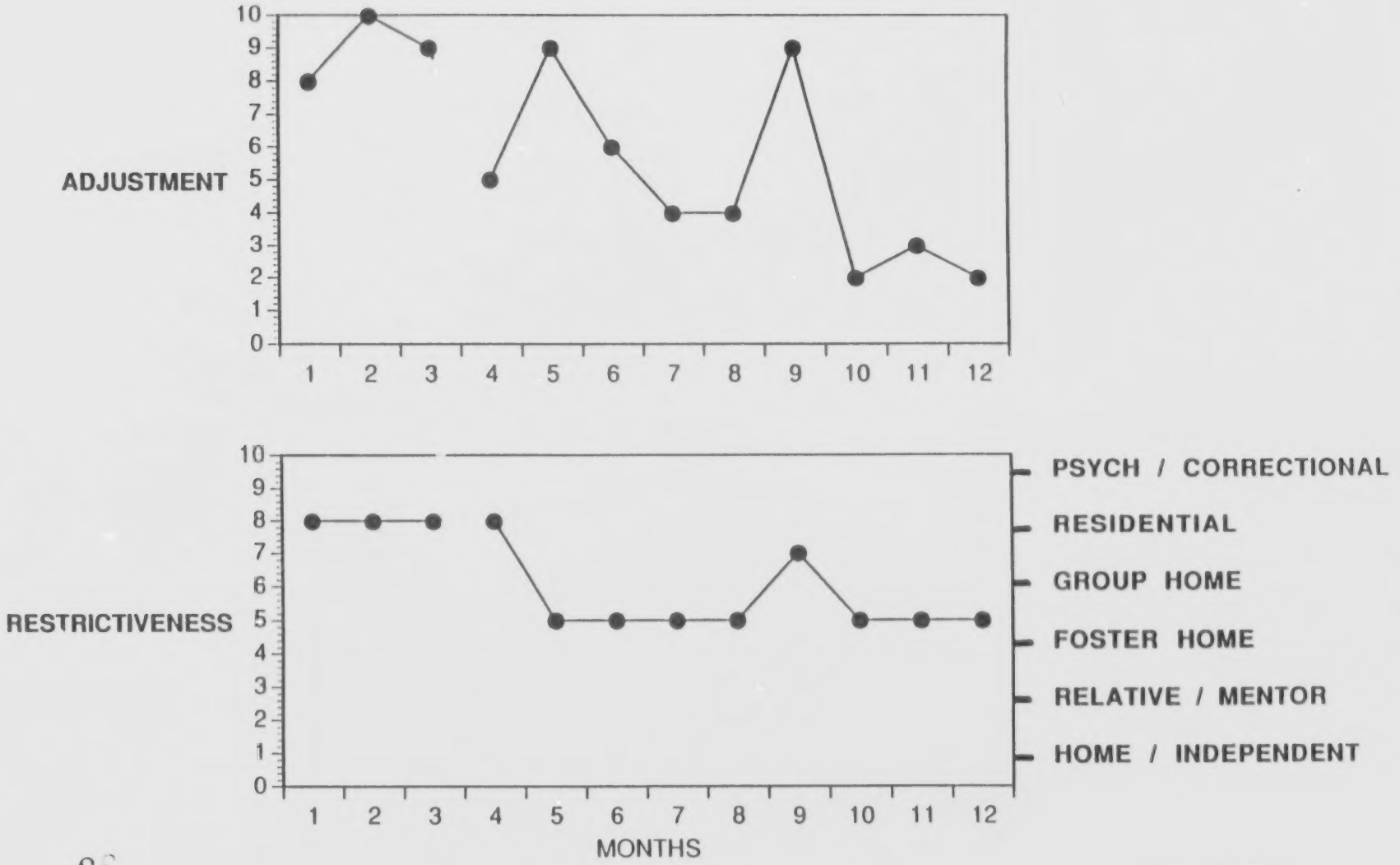
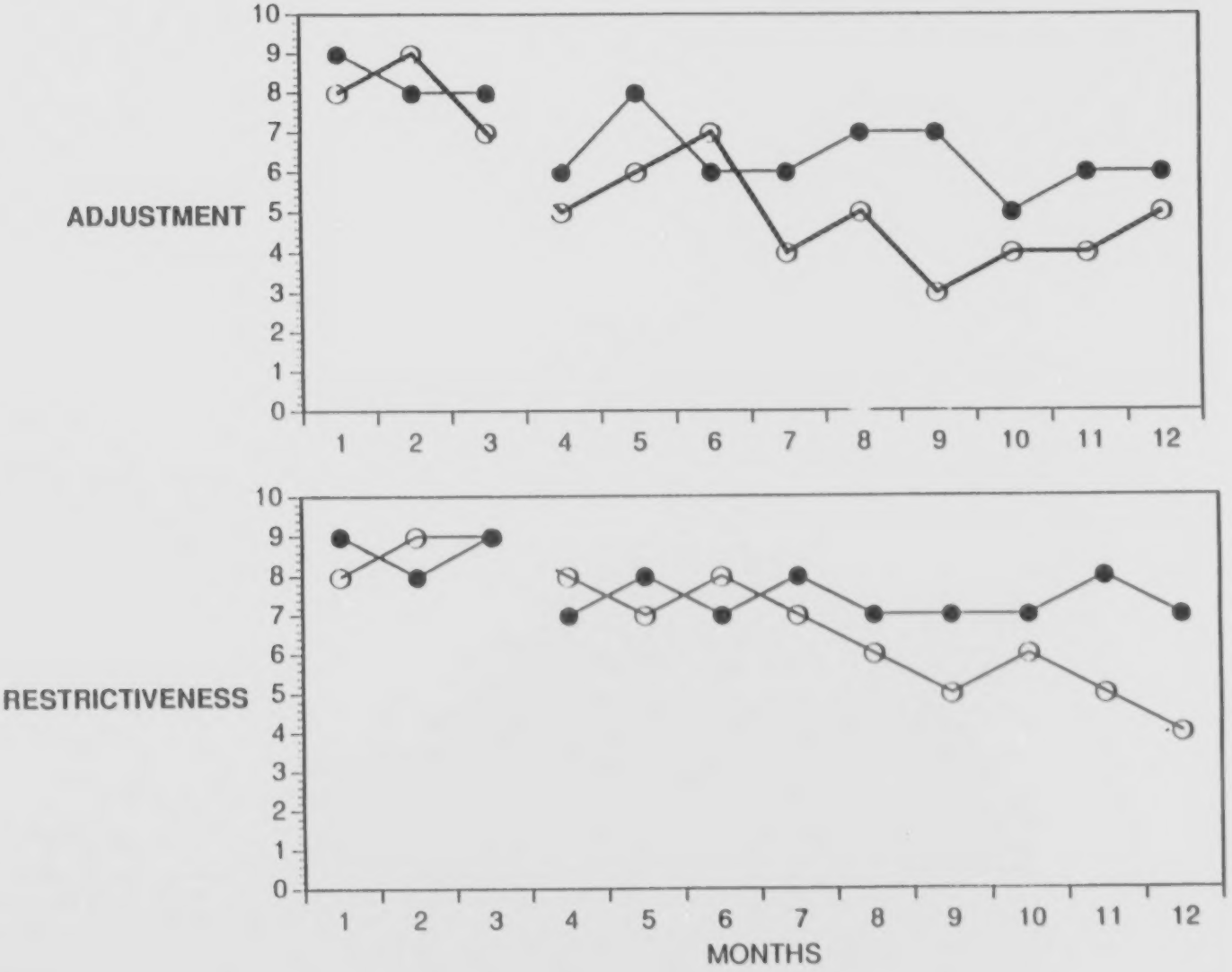
INDIVIDUAL DESIGN



GROUP DESIGNS



TIME SERIES

(COMPARING TRENDS)

ADVANTAGES

1. Data Quantity/Quality

    - more data
    - better reliability
    - better internal validity

2. Ongoing Vs. Time Limited

    - proactive
    - rates of change
    - continuous follow-up

3. User Friendly

    - caseworker/provider
    - legislator
    - policy maker

Disadvantages

- labor
- cost
- norms

Currently, much of the data is collected by undergraduate students involved in a two-semester commitment for course credit. The students train the providers to complete the daily forms, enter the data into the computers, and display it in graphic form. A seminar that goes along with the data collection efforts addresses issues in the system of care for severely emotionally disturbed children.

Dr. Burchard noted that one of the challenges in the evaluation of our service systems is that services are very "component" oriented. A child frequently goes from one service component to another. Therefore, it is desirable to have a system which tracks youngsters across time and across service components. In order to provide individualized care, the money has to follow the child. Similarly, this is a data collection system which also follows the child. Additional information about the Vermont tracking system is provided in Appendix C.

SAMPLING ISSUES

Philip Leaf, Ph.D., Associate Professor
Center for Health Policy and Research
Yale University

Dr. Leaf discussed the importance of the sampling process which involves identifying and allocating potential subjects for the study. He noted that providers may become upset at the prospect of randomly assigning only some of their clients to what is likely to be improved treatment. He suggested framing the issue of randomizing in terms of scarce resources. Given scarce resources, we are working in environments in which we are not going to be able to provide all the services to all children in need. Therefore, randomizing can potentially be seen both as a fair and equitable way of allocating scarce resources as well as a way of learning and drawing inferences from a study over time. Presumably, if it can be demonstrated that the services work, more resources would become available in the future, and additional children would be able to benefit. "One of the things that needs to be discussed in a very straightforward manner with providers, clinicians, and planners is the reality of the situation, that we are not talking about the opportunity to get as much money as we possibly want where everybody could get all possible services. There are limitations. And one of the ways of allocating limited resources in a fair and equitable way is to have some people go into one program and some people go into another."

Dr. Leaf suggested that rather than assigning groups to standard treatment versus a new service approach, studies might consider allocating clients to two competing programs. This approach may be more attractive to providers and families as well as review panels. The two programs may be at different levels of intensity or have different components, and it would be important to learn about the relative benefits of the two programs.

One consideration in the research demonstration project is **where** randomization is implemented. There is not necessarily a reason to randomize clients before they have any contact with the agency or even before they have a prolonged contact with the agency. With regard to the CASSP model, we are interested in how a network of services works. It would be legitimate to look at clients after they have an intake, or after they receive a basic set of assessments, or even after some treatment. At any point in the service delivery process, there may be alternative approaches or services for children, and research could explore how best to utilize these alternatives. There may be points within current service delivery systems where these decisions are already being made and where it would be very important to determine whether a child should receive one set of services or another, or how intensive these services should be, or of what duration services should be. These are all potential points for randomization. Dr. Leaf emphasized that giving children worse possible outcomes as a result of randomization is not acceptable to either providers or researchers. However, there are a lot of points at which randomization can occur, and questions can focus on what aspects of services work and for what types of children certain services work.

Dr. Leaf indicated that in planning a research demonstration project, administrative data is needed in order to ensure that you can get enough children into the project, so that after the three years it will be possible to determine whether or not there was an effect. It is important to specify how children will be identified, the characteristics of children to be included, and any exclusion criteria. There may be reasons to exclude a small number of children with specific characteristics from a broader evaluation that makes the study more acceptable or because the intervention or experimental component of the project is not really what they need. For example, you would not want to randomly allocate children at immediate risk of suicide to a program where someone comes to see them every two weeks.

Sample size is another issue to be considered. In order to increase precision, increasing sample size may be the easiest thing to do, although it often is very expensive. Some of the other things that may be done to improve studies are more difficult, such as increasing the precision of measures. Increasing sample size generates cost both in terms of the services and the evaluation, especially in terms of the CASSP model which talks about multiple services. On the other hand, you do not want to have such a large sample in a research demonstration project that you lose control. Too large a sample may make it difficult to provide a consistent intervention and to control the quality of the intervention. Thus, there is a tension between optimal sample size for a study, how many people can be served, and how much money will be available for the project.

Dr. Leaf noted that there are a lot of questions that we do not need large samples to address, many of which are important questions to policy makers. Generally, we are not measuring subtle symptomatology or subtle changes in children. Rather, these youngsters are failing in school, using illegal substances, getting arrested, being abused, and the like, and it is possible with relatively small sample sizes to find effects relative to these types of indicators. The types of effects we expect from our programs and the costs of these programs are fairly dramatic, and we do not necessarily need large samples.

Sampling for the evaluation must be integrated into the service delivery program. The service program may have eligibility requirements, and therefore some of the intakes in the program may be coterminous with the evaluation. There may be information that is obtained in the identification and assessment of children that is used to define these children as part of the target population. Thus, it is important to integrate the sampling and measurement for the evaluation with the intake and assessment process for the clinical aspects of the projects. This ensures that the procedures used for the evaluation are as natural as possible.

The issue of sampling really comes down to the inferences you want to make, according to Dr. Leaf. You must determine how many people you will need to have in the demonstration project before you are able to draw inferences that are important to you. In research demonstration projects, there typically is a package of services or a program that you want to implement and answer certain related questions -- Did it work? For whom did it work? What were the costs? Did the children who received these services do better than they would have under another legitimate alternative (either the current system if that is seemingly legitimate or another reasonable alternative)? The answers to these questions will inform the further development of service systems, and the sample must be large enough to address the particular questions.

The methods section of the proposal should indicate how you intend to determine whether the services work better for certain groups. Accordingly, the goals and priorities of the project, the sampling, and the analysis plan must be consistent. Dr. Leaf indicated that the fewer aims in a proposal, the better, and the sampling plan should be developed to maximize information about the question that is of primary concern. He emphasized the complexity of our service systems, noting that rather than focusing on the effects of the entire system, it may be appropriate to look at the effects of pieces of the system which are varied for some of the children. It will not be possible to randomly allocate children to one set of programs and then have the schools handle them differently just because they are in your study. Generally, schools will not be part of the fundamental manipulation; they are going to be handling children over time as will juvenile justice systems and child welfare systems. The more complex the question to be studied, the more other parties that may influence the selection of a sample.

It is important to keep in mind that not everybody goes through these programs to completion, since people may drop out or move. Thus, when you determine how many people

you need initially, you must estimate how many people you will end up with due to attrition. The question is not how many people you enroll, but at the points at which you collect data, how many people will you have left. Additionally, you must consider how you will follow those in the study. While those in the intervention may be easier to track, you must also track those in the comparison group who need equal attention in terms of monitoring and evaluation, but who do not necessarily have the same relationship with the agencies involved.

In summary, Dr. Leaf advised handling sampling in a way that there is a comparison between alternatives that is meaningful to the agency and meaningful to the child and parents. This will increase the chances of a successful project as well as your ability to convince a review committee to approve your project. The more policy relevant the proposal and the more consistent the sampling is with the questions being raised, the more likely the proposal will emerge with a positive outcome.

MEASURES/OUTCOMES - SYSTEM OUTCOMES

Michael Hendricks, Ph.D.
MH Associates

Dr. Hendricks reviewed potential measures of system outcomes. These possible measures are arrayed according to CASSP objectives, and are included as Appendix D.

Phil Leaf, Ph.D., Associate Professor
Center for Health Policy and Research
Yale University

Dr. Leaf discussed strategies for measuring the relationships and linkages between organizations as one approach to the measurement of system improvements. He noted that there is considerable experience and expertise in the area of network analysis, although few developed methodologies relate directly to children's services. Ongoing work in the area of interorganizational relationships is being conducted by:

- Joe Morrissey at the University of North Carolina who has conducted a number of multi-county studies and currently is involved in analyzing the Robert Wood Johnson community support projects for mentally ill adults. He has developed a number of instruments for assessing interorganizational connections.

- Oscar Gruske at UCLA's Department of Sociology also has conducted multi-county studies.

- Pat Dorian at the University of Pittsburgh's Department of Sociology is conducting a network analysis in two counties in the Pittsburgh area involving children's agencies.

- Mary Fennel at Penn State University's Department of Sociology.

Each of these individuals has developed somewhat different techniques for assessing interorganizational linkages and different outcome measures.

Dr. Leaf emphasized the importance of assessing the relationships among agencies along a number of different dimensions as well as to utilize a number of different informants -- not just organizational participants, but clients, parents, and funders who will all have different assessments of the linkages and how well services are being provided. In terms of monitoring and understanding the system, it is important to obtain these multiple perspectives. It also is important to assess both positive and negative linkages, the effective aspects of linkages as well as the hindrances to communication and coordination.

Another issue to be considered is "organizational set." Not only do individual agencies have relationships with each other, but groups of organizations tend to form relationships. The pattern of these relationships will influence the ability of the organizations to deliver services and potentially can influence the quality of services. Even when there is a single agency with fiscal responsibility or overall administrative responsibility for children's services, the provider agencies and programs in the community still have a very complex pattern of relationships. Further, an organization may have many formal subparts. Analyzing that pattern of relationships and services is one of the ways of looking at systems, as well as following individual clients through the system.

Additionally, agencies within a community have relationships with regional and state authorities. Within an organizational cluster, there may be agencies with different or

conflicting mandates and with different networks of services. For example, the mental health system may have one network of services and the education system another. An organizational cluster includes all these different networks and how they relate and interact to provide services for individual children.

Some impediments for service delivery arise when the ideology and tasks that are seen as important by different sectors come into conflict. The school, for example, may recognize that children with severe emotional problems have certain needs, but they may see most of those needs being dealt with outside of school due either to the expense of providing services or because they legitimately feel that other agencies could provide better services.

A number of variables relevant to interorganizational relationships are displayed on page 27. They include the formality of the interactions, reciprocity, centrality, conflict, coordination, density (how many agencies are included), multiplicity (how many different types of services), cohesion, etc.

Dr. Leaf noted that, with the exception of Pat Dorian, he is unaware of people who have used network approaches to measure the types of exchanges that would be important to CASSP-type systems of care. To some extent, children's service systems are more complex than adult systems because of the multitude of agencies and organized sectors of society that are brought to bear on providing services to children. However, the involvement of multiple agencies may make the approaches of network theorists even more applicable, because they can serve as an important data reduction procedure.

Dr. Leaf described a technique that has been developed to attempt to define what comprises the system of services in a community. Because the number of agencies that provide important services varies enormously, a snowball technique has been developed. A list of agencies or services from any individual typically would be a very limited list. The snowball technique involves going to clients, families, provider agencies, planning and administrative agencies, funding agencies, etc. to provide lists of agencies and services in the system. This technique yields a more complete identification of all involved services. Respondents also can be asked to rate their satisfaction with particular services in terms of quality and in terms of the positive and negative linkages among agencies.

The person from whom you obtain information about an organization is an important consideration. No one person has all the information, particularly in large or complex agencies. Further, if an agency has a number of different subparts that have important roles in the delivery of children's services, informants must be identified who can provide reasonably good information about each subunit. The director of the agency may not necessarily have information on all the subparts and all the relevant linkages and interorganizational relationships.

Dr. Leaf emphasized that there is no one right way of conducting studies examining interorganizational relationships, although there are some fairly well developed methodologies. He suggested it is important to measure things that are consistent with the priorities of the proposal, the way the particular system of care is conceptualized, and the linkages that are considered most important.

VARIABLES OF IOR STRUCTURE AND PROCESS

Interaction Formalization

Interaction Standardization

Transaction Importance

Transaction Frequency

Reciprocity

Perceived Power

Centrality

Cooperation

Conflict

Coordination

VARIABLES OF NETWORK STRUCTURE

Density

Multiplexity

Cohesion

Reciprocity

Structural Equivalence

Reachability

Centrality

Complexity

Fennell M. & Dockett K. (1990). Interorganizational systems approaches. In J. Morrissey & D. Dennis (Eds.) Homeless and mental illness: Toward the next generation of research studies. Rockville, MD: National Institute of Mental Health, Office of Programs for the Homeless Mentally Ill.

MEASURES/OUTCOMES - CLIENT OUTCOMES

Len Bickman, Ph.D., Director
Center for Mental Health Policy
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Dr. Bickman stated that the measurement of client outcomes is the bottom line. "You can do all the nice system changes, all the brilliant interorganizational networking, all the provision of resources, and do all the things that theoretically or conceptually or as an article of faith you believe in. At some point, we are accountable for saying whether the intervention affected children, if it affected families. Because if it doesn't, then clearly for the last number of years, we have taken a wrong turn. And that, essentially, is the bottom line of questioning the assumptions underlying the CASSP philosophy." CASSP has been based on an orienting philosophy about what we need to do to improve the well being of children. However, from the perspective of evaluators, these are still assumptions. They have not been demonstrated sufficiently, and the purpose of the research demonstration projects is to start looking critically at some of these assumptions. The issue is to look carefully at what we are doing to make sure that what we are doing actually improves the lives of children and families.

There are many instruments and methodologies for the measurement of clinical outcomes. Dr. Bickman advised against designing your own instruments for a research demonstration project. A three-year project is difficult at best. If you spend the first year and a half designing instruments and pilot testing them, there will be little time left for data collection. And you cannot go into the field without an instrument that has already been field tested. While you may include new instrumentation as ancillary instrumentation, the key instruments you use should have a literature published in reputable journals.

Additionally, use of these instruments requires training to administer them, thought about the data analysis process, and a system of quality control for the data collection process. Proposals should go beyond describing the instruments you plan to use and should document your ability to access clients, collect good quality data, and check on the quality of data.

How mental health outcomes are conceptualized often depends on the perspective as shown on page 28, A Tripartite View of Mental Health Outcome. Different stakeholders (client/family, professional, and society) have different views of what they think is important to look at. One domain is psychopathology. From the perspective of the client and family, a reduction in problems and stresses are what they want to deal with. Professionals have categories for describing children, and they look for a decrease in symptoms, severity of diagnosis, and treatment needs. From the societal perspective, the salient outcomes relate to how restrictive the treatment is, how expensive the treatment is, where treatment is provided, length of stay, and how the child deals with the surrounding environment in the community.

Another more positive domain is social competence. From the client's perspective, this involves an examination of self-esteem or how the child thinks about himself or herself, their sense of what resources are available. A professional would judge things like level of functioning and self-esteem, and on the societal side one could look at outcomes like school performance, absences, and teacher ratings.

A third outcome domain of interest is satisfaction. From the client/family perspective, this would involve assessing their satisfaction with services. Professionally, this would involve looking at whether services meet professional standards or the quality of services. In terms of society, this involves looking at whether services meet regulations, licensing standards, and the like.

A TRIPARTITE VIEW OF MENTAL HEALTH OUTCOME: GOALS OF SERVICE

Domains of Functioning	Stakeholders		
	Client/Family	Professional	Society
Psychopathology	Decrease in referral problems, stress	Decrease in symptoms, severity of dx, treatment needs	Less expensive/ restrictive treatment (LOS down), decreased # disruptive community incidents
Social Competence	Feel better/more in control, more resources available	Improved self-esteem, adaptive functioning	Better school attendance, grades
Satisfaction	Satisfied with services	Meets professional standards	Treatment meets standards, regulations

One of the more recent techniques used for measuring clinical outcome is the structured clinical interview. A sample of four such interviews are shown on page 30. This is not meant to be an exhaustive list; there are other structured interviews available. These interviews are practically the only research-oriented way to obtain a DSM-III-R diagnosis that there is some degree of trust in, although you may not need to have DSM-III-R categorization in your project. The chart displays a number of items about each structured interview -- how long it takes to administer, the age range, type of interviewer required, whether it has a parent form, whether it has a training manual, how it deals with individual symptoms, summary scales, and diagnoses. The chart also includes information about reliability and validity and the availability of computer scoring. Included on the chart are the Diagnostic Interview for Children and Adolescents (DISC), the Child Assessment Schedule (CAS), the Schedule for Affective Disorders or Schizophrenia in school age children (K-SADS), and the Diagnostic Interview for Children and Adolescents (DICA).

The data from structured interviews that people tend to use as outcome measures are the symptom severities that provide a sensitive way of looking at the children's perspective. This is the most time consuming aspect of data collection for children and parents, but they provide the most detailed, in-depth information.

Another approach to outcome measurement, which is much less time consuming and easier to administer, is the use of a behavior rating scale. The chart on page 31 provides information about five behavior rating scales in terms of number of items, administration time, appropriate age range, availability of a training manual, who does the ratings, availability of norms, availability of scoring software, reliabilities, etc. The chart includes the Conners Parent Rating Scale (CPRS), the Conners Teacher Rating Scale (CTRS), the Child Behavior Checklist (CBCL), the Teacher Report Form (TRF), and the Behavior Problem Checklist (BPC). Thus, there are a variety of checklists available that are basically self-report. There may be a child, parent, and teacher form available which enables you to collect multiple indices. They are empirically-based instruments in that they are based upon lots of questions asked to children, parents, and others and research to discriminate between clinical and nonclinical populations. They do not provide DSM-III-R categories but rather provide other subscale information about the child. All these instruments are under constant refinement, so you should be sure to obtain the latest version.

There are fewer measurement instruments in the social competence area. The CBCL teacher form has a social skills subscale, and instruments dealing with level of functioning come under this category. Indicators of level of functioning typically are rating scales to be completed by the child's therapist. In addition, an interviewer who conducts a structured interview and collects a lot of data may complete a level of functioning scale after the interview. The Children's Global Assessment Scale provides current level of functioning information, and Vanderbilt University has adapted an adult functional assessment scale for use with children (Child and Adolescent Functional Assessment Scale - CAFAS). Another example of an instrument in this area is the Self-Perception Scale which examines the child's self-concept in areas of scholastic competence, social acceptance, physical appearance, behavioral conduct, and additional dimensions for adolescents such as romantic appeal and job competence. The child or adolescent completes this instrument, and it may be used to show responsiveness to treatment since as they feel better about themselves they may change how they rate themselves.

Family functioning is another relevant area, although measurement in this area has been very difficult to develop. One can see a family as an organization, a small one, but one that contains some of the same characteristics as larger organizations -- complexity, task orientation, and communication patterns. To assess families, it is possible to use observational

STRUCTURED INTERVIEWS FOR CHILDREN

	DISC	CAS	K-SADS	DICA
Number of Items	264	75	100	80
Administration Time	40-60 minutes	45-90 minutes	45-60 minutes	40-60 minutes
Age Range	6-18 years	7-16 years	6-16 years	6-16 years
Interviewer	Clinician or Layperson	Clinician or Layperson	Advanced Clinician	Clinician or Layperson
Parent Form	Yes	Yes	Yes	Yes
Training Manual	Yes	Yes	No	No
Individual Symptoms	Presence/absence onset, duration, impairment	Presence/absence-onset, duration in appendix	Presence/absence: severity	Presence/absence onset, duration
Summary Scales	27 symptom scales	11 content areas 9 symptom complexes	12 summary scales Global Assessment Scale	6 content areas
Diagnoses	DSM-III	DSM-III***	DSM-III	DSM-III***
Test-Retest	moderate**	high*	moderate**	high*
Interrater Reliability	high*	high*	moderate**	moderate**
Discriminant Validity	moderate**	high*	---	moderate**
Concurrent Validity	---	moderate**	---	---
Computer Scoring	Yes	Yes	Yes	Yes

*High: $.66 \leq r \leq 1.00$ **Moderate: $.45 \leq r \geq .65$ ***CAS-R available for DSM-III-R
***DICA available for DSM-III-R

BEHAVIOR RATING SCALES

	CPRS	CTRS	CBCL	TRF	BPC
Number of Items	93	39	138		89
Administration Time	10-15 min.	5-10 min.	15-20 min.	15-20 min.	10-15 min.
Age Range	6-14 yrs.	not reported	2-18 yrs.	6-16 yrs.	5-13 yrs.
Training Manual	Yes	Yes	Yes	Yes	Yes
Rater	Parent(s)/ Caretaker(s)	Teacher(s)	Parent(s)/ Caretaker(s)	Teacher(s)	Parent(s), Teacher(s), Informants experienced with child
Normative Data	Yes (6-14 yrs.)	Yes (4-12 yrs.)	Yes (4-16 yrs.)	Yes (4-16 yrs.)	Yes (5-13 yrs.)
Scoring Software	Yes	Yes	Yes	Yes	No
Treatment Sensitive	Yes	Yes	Yes	No	Yes
Test-Retest Reliability	.85	.70 - .90	.95 (behavior problems) .99 (social competence)	.89	.49 - .83
Internal Consistency	Adequate	Adequate	Adequate	Adequate	Adequate
Interrater Reliability	-----	-----	.978 - .985	-----	.52 - .85 (Teachers) .55 - .93 (Parents)

ratings, structured interviews, observation of families accomplishing tasks, or more standardized questionnaires about family functioning. These latter self-report measures provide the perceptions of family members about what problems they have and how sensitive they are to these problems. Global family functioning can be looked at as a direct outcome of some projects, or in some cases a family measure may be used more as a mediating or moderating variable in the analysis. Thus, it may be important to collect information about the family even though they may not be a direct recipient of services. There are a number of potential instruments including the Family Environment Scale; the Family Assessment Device which deals with problem solving, communication, roles, and effective responsiveness; the Family Index of Regenerativity and Adaptation (FIRA) which looks at seven indices of family functioning such as social support, stress, resources, and level of distress; the Family Inventory of Life Events (FILE) which is a scale that deals with divorce, separation, stress, work and family relationships, illnesses, etc.; and the Family Resource Scale which looks at resources that the family has available including financial support, social support, time, etc.

Another area that may be important to look at is parental pathology because there is some indication that this mediates childhood illnesses and may explain why you have differential effects with different children. There are a number of clearly structured interviews that exist for use with adults, and there are scales like the Brief Symptom Inventory (BSI), the SCL-90-R, and other things on the market that can be used.

There are no standardized measures to measure satisfaction; everyone invents their own which can be problematic. Typically, people rate services very high on satisfaction, particularly on global satisfaction. People tend to be so glad to get some sort of service that even poor services are something they like. There is an instrument called the Consumer Satisfaction Questionnaire, an 18-item scale that looks at satisfaction with services. Dr. Bickman stressed that in assessing satisfaction, this issue of specificity is critical. When you are very specific, the information you obtain is much more valuable than global measures of satisfaction because it pinpoints where the problems are.

In addition, there is information to be collected about the background of the child. Who the child is living with, previous services received, and the like are important questions to ask. At Duke University, an instrument called the CASA is being developed to describe the services that a child has received. Because children typically move around so much, this information is often not obtainable from records. Further, there are behavioral indices that may be important to collect. School performance data (grades, attendance, disruptions at school), criminal justice data, and the like is important, although access might be difficult since some of these records are highly confidential. "This is very powerful to policymakers. Because what does anyone know about a change in symptom level from 148 to 137 being statistically significant? We don't know what it really means. Or satisfaction changing from 4.7 to 5.2. The one thing that we do have in terms of being able to communicate with each other, are things like whether the number of days the child has been in school has increased, whether grades have improved, whether they are being arrested as frequently or hospitalized as frequently. A lot of these types of measures are very important and can be easy to collect in some circumstances."

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INSTITUTIONAL REVIEW BOARDS

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Almost every university has an institutional review board (IRB) that reviews proposed research. These boards vary individually with respect to requirements for different types of research. Research with children is much more sensitive than research with adults, and therefore, IRB requirements may be more stringent. One of the areas of concern is the issue of informed consent. Typically, you will be required to obtain permission from parents and in many cases from the child as well in order to involve them in your research. This usually requires the parent and adolescent to sign a consent form indicating that they understand the risks and benefits of the research and agree to participate. They also need to give informed consent to allow you to have access to their records, and informed consent also is required for any audio or video taping.

IRB approval also is needed to collect data. If you will have access to records that contain personal identifiers, and there is information in the records that could harm individuals if it were disclosed, then a full review is needed. States may have IRBs as well as universities, and approval from both the state and the involved university may be necessary depending upon the circumstances of each proposal. Some IRBs require letters indicating cooperation from all institutions involved in the study before they will grant approval. These institutions may have their own IRBs or internal review boards, and so the research protocol may require approval by a group of people at each involved institution before the state or university will grant approval. Thus, it is important to begin this review process early. The document "Protection of Human Subjects," included as Appendix E, contains special regulations for research dealing with children which specify that the level of risk determines the type of informed consent and permission that are needed.

APPENDIX A

RESEARCH ON SERVICE DELIVERY AND SYSTEMS OF CARE: RECOMMENDATIONS FOR THE NIMH CHILD MENTAL HEALTH RESEARCH PLAN

Research on Service Delivery and Systems of Care:

Recommendations for the NIMH Child Mental Health Research Plan

October, 1989

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Research on Service Delivery and Systems of Care: Recommendations for the NIMH Child Mental Health Research Plan

Purpose and Scope

The National Institute of Mental Health (NIMH) is currently in the process of preparing a children's mental health research plan. This plan will build on the recent report of the Institute of Medicine (IOM) of the National Academy of Sciences, and additional input provided to NIMH.

The specific purpose of this paper is to aid in creating the NIMH research plan by providing recommendations on service delivery and systems of care research in children's mental health. The paper is an expansion of the IOM report in this area, and is a response to a request by the Director of NIMH for recommendations on service delivery and system of care research.

The report is prepared by the Research and Training Center for Children's Mental Health at the Florida Mental Health Institute, University of South Florida. It is based on information received from a broad range of individuals in a short-time period. This paper is intended to identify critical issues and themes for research in this area, and discuss resources and funding mechanisms needed to support this research. It is neither intended to be a comprehensive review of existing knowledge in this area, nor a detailed long-term plan for future research.

Further, this report is intended to specifically identify the opportunities and needs for research in service delivery and systems of care for children's mental health. The resources that this report identifies as being needed are intended to be new resources. They are above and beyond existing resources for this important area and also above and beyond the resources already being used or requested for such important areas as clinical research, the Child and Adolescent Service System Program (CASSP), services research for adults, and general support of clinical and research training.

Background

Service Development: At the outset of the 1980s, as documented in a report done for the Children's Defense Fund by Jane Knitzer, the status of services for children with emotional disorders and their families was grossly inadequate. In most communities the only service option available was infrequent, office-based outpatient treatment or hospitalization, with the consequence that there was an excessive reliance on hospitalization. Many states did not have a single full-time children's mental health staff person in their state office, only seven states had made significant progress towards developing a continuum of services, and collaboration between public agencies to meet the needs of children was the exception rather than the rule.

Since that time, assisted greatly by NIMH, and particularly NIMH's CASSP initiative, there has developed a tremendous increase in interest in the needs of children with emotional disorders and their families. States have strengthened their capacity to provide leadership in this area, new service models have been developed that provide intensive services in home and community-based settings, models of a system of care have emerged, the role of parents has been re-defined, and inter-agency collaboration has become more common. In response to the Mental Health Planning Act (P.L. 99-660), NIMH has taken a clear policy stance emphasizing the need for comprehensive community-based systems of care with a special focus on those children and adolescents with the most serious emotional disorders. In response to this, states have prepared plans that describe the specific system they intend to develop.

Despite the fact that much progress has been made, as the results of a recent study of children's mental health by the U.S. Office of Technology Assessment indicates, "The majority of children with mental health problems fail to receive appropriate treatment. Many of the 6 to 8 million children in our nation who are in need of mental health interventions receive no care; other children, perhaps 50% of those in need of treatment, receive care that is inappropriate for their situation" (Saxe, 1987). Part of the inadequacy of care clearly relates to lack of resources; another major factor, however, is the inadequate knowledge base both about the causes and treatment of emotional disorders, and the mechanisms for establishing and maintaining responsive and effective service delivery systems.

At the same time that the public mental health sector has been emphasizing the need for community and family-based systems of care, the 1980s have been a time of rapid and enormous growth in free-standing psychiatric hospitals for children. For-profit hospital chains have expanded around the country, and the number of admissions to these hospitals for children and adolescents has increased dramatically despite the lack of evidence about their effectiveness (Burns & Friedman, 1989; OTA, 1986).

Recent summaries of epidemiological research on point prevalence of emotional disorders have come up with estimates in the general range of 14% to 20% (Brandenburg, Friedman, & Silver, in press; Costello, in press). As the IOM report indicates, "The magnitude of the problem of childhood mental disorders is only partially reflected in epidemiological data about prevalence and incidence of disorders. Substantial evidence suggests that many childhood disorders extend into adulthood either because of their chronic course or because of their adverse effects on the child's development (Kazdin, 1989). Moreover, enormous financial and social costs can be associated with mental disorders in children and adolescents." While making this point, the IOM found it difficult to quantify the actual financial and social costs at this time because the needed information is not available.

<u>Developments in Services Research:</u> Given the human and financial costs of disorders in children, given the scope and magnitude of

the problem, and given the increased interest in improving services, there is now and has been a tremendous need for research on service delivery and systems of care. This is particularly the case because of the special dependent status of children, the wide range of needs that they have and the complex web of statutes, policies and agencies that have been created to respond to these needs. Yet despite this need, until the last few years there has been almost a total absence of research on service delivery and systems of care.

It should be noted in this regard that research on service delivery and systems of care in mental health is a new area, having a much briefer history than the longer established traditions of basic and clinical research. In fact, not only is it relatively new but it had its origins primarily in providing a "real world" test for new developments emanating from clinical research. However, there have been at least four significant developments at a service and policy level that have recently converged to create a strong need for more and better services research.

First, the primary locus of treatment in the mental health field has moved from hospitals to community settings. This has created new challenges in understanding how to develop effective community systems. Second, public mental health systems have identified as their top priority the improvement of services to individuals with severe and persistent problems. Many of these individuals require services from a variety of different kinds of agencies over an extended period of time, thereby creating a need to take a multi-agency look at system development. Third, the role of states in planning and administering mental health services has grown with the implementation of the Alcohol, Drug Abuse, and Mental Health Block Grant program in 1980. This provides a more centralized responsibility for policy-making and planning. Fourth, there has been a rapid escalation of costs for health care in general, including mental health care. As a consequence, there has developed a need for research on such issues as approaches to cost containment, and the impact of different reimbursement strategies on service delivery.

Among the impediments to research on service delivery and systems of care in children's mental health have been the lack of researchers trained in this area, and the lack of opportunities for those with interest and skill. Despite this, however, the second half of the 1980s have seen an increase in such research. Positive results from the NIMH Public--Academic Liaison (PAL) initiative, announced by NIMH in 1988, were seen in some states very rapidly in the form of increased collaborations between university-based researchers and policy-makers. In February, 1988, the first national conference on services research was held on the theme of building an empirical base for service development. The third such conference will be held in February, 1990, and the number and quality of research submissions has steadily gone up for these conferences. In keeping with the theme of the NIMH PAL initiative, these conferences have brought

together a combination of university-based researchers and public policy-makers.

In December, 1988, NIMH issued a targeted research announcement calling for proposals dealing with mental health services for children. An indication of the interest in this type of research is that 29 proposals were submitted, with eight receiving funding. In identifying their priority concern, State Mental Health Representatives for Children and Youth included the need for better research and evaluation as a high priority, and clearly state policy-makers have demonstrated a receptiveness to collaborating with university-based researchers. Further, technologies for conducting service system research, while still in need of further development, have made significant progress, particularly in critical areas such as outcome measurement.

All signs suggest that there is both a need and a unique opportunity for research on service delivery and systems of care. On the one hand, there is growing interest within the academic research community. On the other hand, policy-makers and advocates, working together to build the most effective systems that they can amidst rapid change, are eagerly seeking a strong research foundation for the system.

Method

Input for this report was provided in several ways. The major intent was to gather ideas from a broad range of individuals within a short-time period. This includes researchers involved in services research from a variety of academic disciplines, state-level policy makers in children's mental health, researchers within state departments of mental health, parents, advocates, representatives of national organizations involved in policy development, and administrators of local mental health programs.

First, a meeting of 15 researchers, policy-makers, and advocates was held in Alexandria, Va. on October 3, 1989 to discuss major issues for which research is needed, and resources and funding mechanisms to support such research. Second, in order to expand the number and range of people consulted, a series of in-person and telephone interviews were conducted with approximately 25 other individuals from around the country. Third, a draft paper was distributed to a group of 20 individuals for their comments and recommendations. Fourth, the draft paper was reviewed at the meeting of the Advisory Board for the Research and Training Center for Children's Mental Health in Tampa, October 15 and 16, 1989. Altogether, as indicated in the list in the Appendix, over 50 individuals participated in the process of developing this report in a short time period.

Recommendations

This section will first identify the substantive areas consistently identified as being in immediate need of research attention. These are not only important areas of need but also

represent areas in which the technology is sufficiently advanced and the manpower is available for a substantial contribution to be made. The section will then discuss funding mechanisms to support such research. This will lead to a discussion of research training needs in the field, and finally, to a specific recommendation of the financial resources needed to support the proposed activities.

Focus of Research: Although many potential focuses for research were identified during this process, it is striking that there was significant consensus in the identification of priorities by participants in the process. Eight major themes, which are clearly overlapping, were identified and are presented here without any attempt to further prioritize them.

1) **Research on the Effectiveness of Strategies to Provide Alternatives to Residential Treatment through Comprehensive Community-Based Systems**--In many states, currently two-thirds or more of the children's mental health budget is allocated to residential or hospital treatment. As the Invisible Children Project of the National Mental Health Association reports, about 5,000 children are placed out of their own state each year in residential treatment facilities. Given the scarcity of dollars, the high cost of residential and hospital treatment, and the lack of research to document its effectiveness, many state policy-makers and advocates are seeking to develop systems of care that provide cost-effective alternatives to residential treatment. States and communities have developed a range of approaches to this problem, including modifying the array of services provided, the manner in which the service delivery system is organized, the reimbursement mechanisms, and decision-making processes about the need for residential or hospital treatment. Given the policy emphasis placed within many states and within NIMH (e.g, P.L. 99-660) on the need for systems of care, there is a parallel need now for research that will use the overall community-based system as the unit of analysis rather than focusing only on specific service components or procedures. The Mental Health Service Program for Youth of the Robert Wood Johnson Foundation provides a natural and rich opportunity for research of this type on community-based systems. This is an area of research that is very complex and clearly calls for a strong public and academic collaboration. An important theme within this research, as well as the other research topics, should be the tangible financial impact and the overall social and emotional impact of the services on families as well as on children.

2) **Research on the Effectiveness of Innovative Service Approaches**--The 1980s have seen the expanded use of a range of innovative services for children with serious emotional disorders and their families. These include intensive home-based services, therapeutic foster care, respite care, family support, day treatment, mobile crisis services, case management, and individualized treatment using flexible funds. For some of these newer approaches there is an accumulating body of program evaluations that suggest their effectiveness. For the most part,

however, the research base on the overall effectiveness of these approaches in relation to other services, and on the effectiveness of specific models is inadequate. In addition, this is an area that provides rich opportunities to integrate clinical research with services research by examining the effectiveness of particular approaches with youngsters whose problems are well-defined and to examine both quantitative outcomes and quality of service. As with the first area mentioned above, there is also clearly a need for the research on these services to have a strong longitudinal follow-up component.

3) **Research on the Effects of Different Reimbursement Mechanisms and Funding Strategies**--Within recent years there has developed an increasing awareness of the impact of reimbursement mechanisms and funding strategies on service delivery. For example, in testimony before a congressional committee the senior author of the U.S. OTA report indicated that, "The reasons for the present inefficient and ineffective system are many, but one is increasingly central: Our methods for paying for mental health care. Rather than children's needs being paramount in deciding whether and what type of treatment will be proffered, treatment decisions are increasingly driven by the health care reimbursement system" (Saxe, 1987). There are a variety of issues that are of critical importance under this general heading. These include strategies for developing benefit packages both within the public sector (e.g., Medicaid and Champus) and the private sector (e.g., major private insurance carriers) that will provide incentives for use of home and community-based services, the advantages and disadvantages of managed care approaches, the actual direct and indirect costs of emotional disorders to families, public agencies, and third-party providers, the impact of different state funding strategies on service utilization at a local level, and strategies for providing quality care to children and families without any insurance coverage. Despite the importance of these issues, and other related financing topics, this has essentially been a dormant area of research in the children's mental health field.

4) **Research on the Effectiveness of Approaches to Involving and Supporting Families**--During the 1980s there has been increased recognition of the great burden that is created for families of youngsters with emotional disorders. The sacrifices that families make are often overwhelming and these can quickly become public problems as well. For example, it is not unusual for families to become bankrupt because of the costs of care, many times parents must quit their jobs or reduce their work hours in order to fill the gaps in care between fragmented formal programs, and stresses related to caring for children with emotional disorders frequently contribute to marital problems (Friesen, 1989). There has also developed a greater recognition of the potential benefits to families and children of providing services that are not only family-based but supportive of families. These developments have occurred, however, largely without the support of research to examine the relative efficacy of different family support approaches, the impact of different strategies for involving families in case planning and

decision-making as partners with professionals, barriers to care from a family perspective, and the effect of different organizational structures and practices on the responsiveness of service systems to the needs of families. Important issues such as the effect on families of parents having to relinquish custody of their children in order to secure special services are in great need of study. In addition, rather than the family perspective serving as an important beginning point for conceptualizing research, it has been virtually ignored. There remains now a major challenge to incorporate the family perspective both in establishing overall research agendas and in designing specific research projects. In addition, there remains also a need to assess the impact on family members of having a child with a serious emotional disorder, and the impact of various services and policies on family members.

5) Research on the Effects of Multi-Agency Collaboration in Identification, Referral, and Treatment of Children with Emotional Disorders--There is a consistent body of research that suggests that children with emotional disorders tend to be under-identified as needing help by primary care physicians, educators, and child welfare staff, for example. While there has been some research on this topic, there is clearly a need for additional research to identify barriers to proper identification by non-mental health professionals, and to assess strategies for strengthening appropriate identification and referral. While the issue of identification is important, another critical issue for research is strategies for producing effective collaboration in actually serving youngsters who may already be receiving services from more than one agency, whose problems require services from multiple agencies, or who are dually diagnosed. Particularly amongst children with the most serious emotional problems, there is almost inevitably a need for services from agencies other than mental health, be it special education, child welfare, juvenile justice, substance abuse, or primary health care. The inadequacies of any single system add to the need for services from the other systems. In recognition of this, across the country there have developed a number of strategies for jointly funding services, for combined case planning on individual youngsters, for clarifying roles and responsibilities of different agencies, and for promoting closer collaboration. Yet despite the importance of this area, and the enormous range of activities that have been initiated to improve collaboration, there is little systematic research either on strategies for achieving such collaborations, or their actual effects on children and families.

6) Research on Services to Minority Children and their Families--A major focus of the NIMH CASSP initiative is to work towards the development of a system of care in which services are geared to the varied needs of the culturally diverse population in the United States. As our population becomes increasingly more diverse, the need to develop and evaluate different strategies for increasing the flexibility and cultural appropriateness of services for minority children and their families grows as well. Other research needs include studying

the differential treatment within the mental health system of children and families from different ethnic and cultural backgrounds, assessing the effectiveness of policy and training strategies to produce a system that is more responsive to minority children and their families, and examining the different manifestations of pathology in different cultures. It is recognized that within NIMH there already exists a focus on research on minority issues in mental health; at this point there is a great need for increased emphasis, particularly as pertains to the organization of service delivery systems.

7) Research on the Organization of Services--The organization of a service system to provide services to children with emotional disorders and their families is highly complex. There are many variations in such issues as the nature of responsibilities of different state agencies, the relationship between the state and local levels, the relationship between the judicial and executive branches of government, and the existence of particular formal or informal structures to promote inter-agency collaboration. Even within different school systems in individual states there is considerable variability, despite a common federal policy structure on education of children with handicaps. A recent trend within states is to explore the advisability of re-structuring their service system to create a consolidated children's agency that provides mental health services as well as other services. Yet at this time there is very little research to guide policy-makers as they address this and other very important but complicated organizational issues involving different levels of government and different systems of service.

8) Research on Assessment, Case Planning, and Clinical Decision-Making--The manner in which information is gathered about children by service providers, treatment plans are developed, and decisions are ultimately made is very important and also very under-studied. The Invisible Children Project of the National Mental Health Association found that most states had no formal, standard practice that they followed in deciding whether youngsters should be placed in residential treatment. Amongst those states that do have such a procedure, the procedures are considerably varied. Further, although there has been considerable progress made in clinical assessment under controlled conditions and in innovative projects, there is almost no information about the state of assessment practices around the country, or the impact of different practices. Further, creative case planning has been identified as a key requirement for effective service provision but there is very little known about case planning as it is currently practiced, or as it should be practiced. This is an area of research in which the opportunities and the need are both clearly there.

Methodological Research--In addition to these eight substantive areas, an important need for more methodological research was identified with two particular focuses. The first focus was the need to develop improved methodologies for describing and measuring community-based systems of care. The

absence of such methodologies impedes progress in research in which the basic unit of analysis is the system of care rather than smaller components of it. Given that the policy focus both at a federal and state level is on the development of community-based systems of care, it is imperative that more methodological research be done in this area. Such methodologies would need to be able to describe the formal structure of systems (e.g., the existing agencies, funding mechanisms, decision-making processes, inter-agency agreements, statutes), and the actual workings of the systems (e.g., the actual identification and referral practices, the nature of the interactions between agencies, the development of service plans, and the current patterns of care seeking).

The second focus was the need to refine methodologies for assessing cost-effectiveness and cost-benefit of services. Although progress has been made in this area, the complexity of determining precisely which costs should be included, how those costs should be calculated, how indirect costs should be assessed, and how different outcomes should be compared to costs still presents a major problem. While there is a clear consensus on the importance of research that looks at cost-effectiveness and cost-benefit of services, there is also agreement on the need for more methodological research to advance the field.

Since research on service delivery and systems of care is ultimately intended to result in an improved system of services, there is a special need to emphasize the importance of supplementing traditional approaches to dissemination (e.g., publications in refereed journals, presentations at professional conferences) with non-traditional methods. Policy-makers are a major consumer of this type of research, and while they appear eager to get the new information the traditional methods of dissemination are generally ineffective in reaching them. It therefore becomes important that as part of an increased emphasis on service delivery and systems of care research there be a parallel emphasis on disseminating information more directly to planners and policy-makers. This can be done through such mechanisms as brief, non-technical publications distributed directly to the target audience, and through presentations at meetings traditionally attended by planners and policy-makers.

Overall, as the last two methodological issues illustrate, it is important to emphasize that in research on service delivery and systems of care the precise specification of variables and measurement procedures are intrinsically extremely complex. Also, when the unit of study is some aspect of the service system, the opportunity for the researcher to control all of the critical variables is not as great as in basic or clinical research. In addition, from a developmental standpoint this field of research specialization is still in its early stages of growth. While these conditions create special challenges for researchers in this field, they are not insurmountable and there is no question of the need for more research of the type described here if a strong empirical foundation for service development is to be established. Both in terms of its

understanding of the substantive issues and its ability to deal with the methodological challenges, the team of academic researchers working in combination with policy-makers, agency-based researchers, parents, and advocates appears ready to develop research proposals that will significantly advance the field.

Funding Mechanisms: There are a number of different funding mechanisms for support of system of care and service delivery research, most of which already exist, which are needed. These include the following:

1) Individual Project Grants--This is the primary funding mechanism for NIMH research. This is an important and appropriate mechanism which needs to be expanded in order to more adequately meet the need in the field and capitalize on the present opportunities. In addition to the expansion of this research support mechanism, it is important to insure that there be an ongoing peer review committee composed primarily of experts in services research in the children's field. Given the complexity of this field and the differences between it and the adult field, a fair, knowledgeable and consistent review process requires a standing multi-disciplinary committee specifically for children. Such a committee was constituted on a special basis for the recent special announcement issued by NIMH (December, 1988) for services research in child mental health, and a similar committee should now be established on an ongoing basis.

2) Center Grants--The mechanism of funding research centers is particularly important in this field given the need for teams of researchers from both traditional mental health disciplines and other disciplines (e.g, economics, sociology, education). NIMH currently funds five centers for research on the organization and financing of services for the seriously mentally ill. While the center model as utilized by NIMH is a valuable one, and several of these already-funded centers are initiating projects for children, children's research represents a small part of their agenda. There is a new for capitalizing on this important mechanism by funding research centers specifically on service delivery and system of care research in children's mental health while at the same time creating new opportunities for existing centers to focus on children.

3) Service Demonstrations--This is a mechanism that is not currently available through NIMH support in the children's mental health field although a recent grant announcement was issued for such projects for adults through the NIMH Community Support Program. This type of mechanism provides funding for service demonstration projects that include a strong research and evaluation component. Such a mechanism is particularly ideal for research on the efficacy of innovative service approaches, such as some of those highlighted by the NIMH CASSP initiative (Goldman, 1988; Stroul, 1988 & 1989; & Stroul & Friedman, 1986), for research on alternative approaches for supporting families, and for research on approaches to serving minority children and their families. The support of such projects is a logical

extension of the NIMH CASSP effort. It is important to emphasize, however, that it should be developed not as a replacement for existing CASSP activities but as an important research--demonstration extension of CASSP with additional funds.

4) Small Grants--This grant program has recently been modified to allow for funding of grants for up to two years at a maximum of $50,000 per year. A special advantage of these grants is that the time for their review is only about four months. The relatively rapid turnaround time for these grants, and the new potential both in terms of duration and amount of funding makes this a valuable funding mechanism. It can be particularly helpful in the early stages of relationship-building between university-based researchers and public agencies by providing funding for small-scale projects that can later be expanded through other research support mechanisms. Also, there are growing opportunities in the field to advance knowledge by capitalizing on naturally-occurring experiments as important changes are made within service systems. This grant mechanism provides a means for public agencies and universities to collaborate in a relatively short-time period on meaningful studies to take advantage of the opportunities presented by these changes. In order for this to be an effective research support mechanism, however, it is essential that there be not only a quick turnaround time but a review by a committee that is expert in services research.

5) Inter-agency Research Support--NIMH is the federal agency with the strongest commitment to children's mental health and the greatest talent and technical resources to address this area. However, many other federal agencies share a strong interest in increasing the knowledge base for serving children with emotional disorders and their families. This includes groups within other ADAMHA institutes, the National Institute of Health, the Administration for Children, Youth, and Families, the Bureau of Maternal and Child Health, the Department of Education, and the Department of Justice. The field would greatly benefit from NIMH assuming a strong leadership role in developing a multi-agency services research agenda at the federal level, and developing mechanisms for multi-agency review and support of proposals. An important precedent for this is the joint funding of two research and training centers in children's mental health by NIMH and the National Institute on Disability and Rehabilitation Research of the Department of Education.

In addition to these mechanisms, other important means of supporting research include research training grants and career development awards. Research training grants are discussed in the next section. There are two primary types of research career development awards with the general goal of enabling researchers to engage in research on a full-time basis over a period of time. One broad category is the individual career development awards that serve an important purpose in supporting researchers who

have completed their training and are now seeking an opportunity to devote their full-energies to research over an extended period

of time. The second type of award is the First Independent Research Support and Transition (FIRST) award which is more specifically designed to provided an initial period of support for a newly independent researcher. These awards may provide support of up to $350,000 for five years.

Research Training: While it is clear that the field is ready for significantly expanded research in service delivery and systems of care for children, it is equally apparent that the future growth and development of this field requires a strong commitment to research training across a wide range of disciplines, and support of beginning researchers. This support of research training is required both at the pre-doctoral and post-doctoral level. This report is in full support of the emphasis with the IOM report on the importance of this area but goes beyond the report to specifically address research training for service delivery and system of care research.

The specific mechanisms needed to support enhanced research training are varied. They include training grants to institutions for pre-doctoral and post-doctoral training, and the support of multi-disciplinary services research training centers. They also include and should emphasize training opportunities for minorities.

It is essential that these awards for research training have a broader focus than the traditional mental health disciplines. They may conceivably include such disciplines as anthropology, sociology, economics, education, and health policy and management, for example. At a post-doctoral level, it is particularly recommended that research training centers be supported with a multi-disciplinary focus. Such multi-disciplinary services research training centers need not have an exclusive focus on children; it is essential, however, that they be required to have a significant focus on children.

Funding Amounts: The previous sections of this paper have discussed the important themes within service delivery and system of care research for children, research support mechanisms, and research training. This section provides specific recommendations for funding amounts. These are offered for the different research and research training support mechanisms.

Research Support--In response to its recently issued announcement for services research, NIMH received more proposals that were approved than it was able to fund. It actually provided approximately $2 million in funding. This announcement, along with other developments in the field such as the NIMH PAL initiative and the Robert Wood Johnson Foundation Mental Health Services for Youth grant program, continue to attract growing interest not only from university-based researchers but from teams of academicians and staff from public agencies. Further, activities such as the Robert Wood Johnson grant program provide excellent opportunities for research that extend beyond the evaluation that will be directly funded by the foundation. Given these new opportunities in the field, and the

response to the last special NIMH announcement, it is recommended that in Year One Research Support for Individual Project grants be $5 million. This should be expanded by $3 million per year to a total of $17 million by the end of the five year plan.

In addition, it is recommended that NIMH support four research centers specifically for children during year one. Given the cost of conducting research on complex service delivery systems, it is recommended that they be funded during the first year at $1 million each for a total of $4 million. In addition, to encourage that existing centers increase their focus on children, it is recommended that there be an additional $1 million to supplement funding of existing NIMH-supported research centers for the organizing and financing of services. This raises the total cost for year one for centers to $5 million. There should be an additional two centers added during year two and year three each for a total of eight centers plus supplemental funds to existing centers at a cost of $9 million. Clearly the Center mechanism is extremely important for supporting the development strong multi-disciplinary research teams with an ongoing program of research. The response to the previous NIMH center announcements have indicated that such announcements have great potential for facilitating the assembling of such teams, but primarily around the needs of adults to this point.

Next it is recommended that NIMH support ten service demonstration projects at an average cost of $400,000 during the first year for a total cost of $4 million. This should be increased by five new projects per year for a total of 30 projects and $12 million after five years. The response of the children's field indicates a readiness and eagerness to undertake service demonstration efforts, and the response to the service demonstration announcement for CSP shows a willingness and ability of the field to develop demonstration efforts with strong research components. There is an enormous need for such projects, particularly given the changing configuration of services and needs. For such projects to both have a strong research component and mount a meaningful service demonstration, there is a need for an average of $400,000 per project. It is important to emphasize again that this request is for new money for service demonstration projects. While these projects represent a logical extension of NIMH-supported CASSP activities, they should extend and not replace existing CASSP activities.

In the small grant area, it is recommended that there be $1 million in research support during year one. This will provide for 20 grants at $50,000 per grant. The small grant program provides an excellent opportunity to build strong academic--public sector linkages, and to strengthen the existing knowledge by taking advantage of naturally occurring system changes. This mechanism will not only be well-utilized but will further the achievement of the objectives of the PAL initiative. These grants should be increased by 10 per year for a total of 50 grants for $2.5 million after five years.

The next research support mechanism is inter-agency grants. The development of effective inter-agency support mechanisms is more time-consuming than the expansion of the existing mechanisms. It is recommended that during the first year NIMH utilize its leadership to develop an inter-agency research agenda along with appropriate funding mechanisms. No funds for actual research support are requested. However, it is recommended that during year two there be $3 million in research support for ten projects at an average of $300,000 per project, and that this be expanded by ten projects each year for a total of $12 million by the end of year five.

It is recommended that 10 individual Career Development Awards in services research be awarded during year one at $100,000 each for a total of $1 million. This will provide important and much-needed support for researchers who have completed their training and are now seeking an opportunity to devote their full-time attention to their research career. Having invested in the training of these individuals, it is important now to provide mechanisms to support them in critical stages of their career. This should be increased by 10 awards per year until there are 50 such awards by the end of the fifth year for a total amount of $5 million.

The final support category for research is FIRST awards (First Independent Research Support and Transition awards). It is also recommended that $1 million in support be provided during the first year with this increasing to $3 million by year five. The average cost per grant in this category would also be $100,000.

It should be noted that the recommendations here focus exclusively on external support of research. Clearly for the necessary expansion to take place there is a need for internal expansion within NIMH as well. In particular, there is a need for NIMH to add full-time staff with expertise in service delivery and systems of care research in children's mental health to provide technical assistance to potential grantees and to organize and administer the research programs.

In summary, the following recommendations for research support are made:

Funding Mechanism	Year One	Year Five
Individual Project Awards	$ 5.0	$17.0
Center Awards	$ 5.0	$ 9.0
Service Demonstration Awards	$ 4.0	$12.0
Small Grant Awards	$ 1.0	$ 2.5
Inter-agency Awards	0	$12.0
Individual Career Development	$ 1.0	$ 5.0
FIRST Awards	$ 1.0	$ 3.0
Total	$ 17.0	$60.5

Research Training--For research training the only general category to be included here is support of Institutional Training

Grants for both pre-doctoral and post-doctoral research training. This includes support of multi-disciplinary training centers for services research and support of research training for minorities. It is recommended that there be awarded 15 grants during year one specifically for services research at the average amount of $500,000 for a total of $7.5 million. This recommendation is based on the virtual complete absence of support at present for research training in this area. Given the importance of developing a strong corps of well-qualified scientists to do this important but complex research, it is further recommended that this be increased by six awards per year for a total of 41 grants and $19.5 million in year five.

Summary: Overall, the recommendations call for support during the first year of $24.5 million of which $17 million is for research support and $7.5 is for support of research training. By the end of year five, these recommendations call for $60.5 million in research support and $19.5 million in research training support for a total of $79.5.

These figures, while reflecting a large increase over present spending, are modest in relation to the direct and indirect cost to individuals, families, and society of emotional disorders in children and adolescents. There are many individual states, for example, that spend more public money per year just for psychiatric hospitalization for children from both state and federal sources than the total requested allocation for research and research training support. Further, these figures are even more modest considering the complexity of the service delivery mechanisms in the children's mental health field with the multiplicity of agencies and services involved. Clearly in virtually any other area of health care the expenditures for research on the service delivery mechanism would dwarf the comparable expenditure in children's mental health. Particularly as progress is made in the basic and clinical research areas in mental health, it will be tragic if the knowledge base in the service delivery and system of care area has not kept pace so that the field is ready to fully capitalize on the new knowledge on behalf of children and their families.

This is an unusual time in that recent years have seen much productive activity in the children's service delivery sector, state policy-makers are seeking empirical findings to assist them in their difficult jobs, parents and professionals are beginning to form powerful and effective partnerships, the technology of services research is making significant progress, and academicians and public administrators are sitting together to address problems of mutual concern. The proposed program of support for research and research training will be an important step towards responding to the enormous need, and capitalizing on the unusual opportunity that is present.

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APPENDIX B

ISSUES IN RESEARCH DESIGN

ISSUES IN RESEARCH DESIGN

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SIX IMPORTANT QUESTIONS

Questions About the DEMONSTRATION

1. What do I want to change?

2. How can I measure these changes?

3. How can I intervene to produce changes?

Questions About the RESEARCH DESIGN

4. How can I detect any changes which do occur?

5. How can I be certain that my intervention caused these changes?

6. How can I ensure that others can learn from my success?

QUESTION #1 - What do I want to change?

Level of focus:

* State-level system changes
* Local-level system changes
* Service delivery changes
* Client outcome changes

"Unit(s) of analysis":

* Systems
* Families
* Children

Specific problem(s) to be addressed

Magnitude of the problem(s)

Trends

QUESTION #2 - How can I measure these changes?

Validity (measures what it is intended to measure):

* Consistent with common usage
* Consistent with alternative measures
* Internally consistent
* Predicts future behavior

Reliability (produces same results repeatedly):

* Composite measures better than separate measures
* Multiple measures better than single measures
* Uniform data collection techniques

Sensitivity to change:

* Range of possible responses
* Continuous measures better than categorical ones
* Guard against "ceiling" and "floor" effects

QUESTION #3 - How can I intervene to produce changes?

Concept:

* Theoretical base
* Clear "program theory" of key elements (no "confounding")
* Powerful intervention

Implementation:

* Feasible (experience, resources)
* Consistent
* Abrupt
* Monitored
* Documented

Little "diffusion of treatment":

* Resentful demoralization
* Compensatory rivalry
* Attempts to equalize treatments

QUESTION #4 - How can I detect any changes which do occur?

"Statistical power" depends on:

* Sample size
* Effect size
* Tests conducted
* Alpha level

Sample size:

* Most common change
* Can be hard to increase
* Technical issue (see book review)

Effect size:

* Actual effect
* Integrity of treatment (strong, consistently delivered, not diffused)
* Data collection (consistent, sensitive, at maximum impact)

Tests conducted:

* Parametric better than non-parametric
* Blocking, covariates, variables in regression equations (stratified sampling)
* Repeated measures

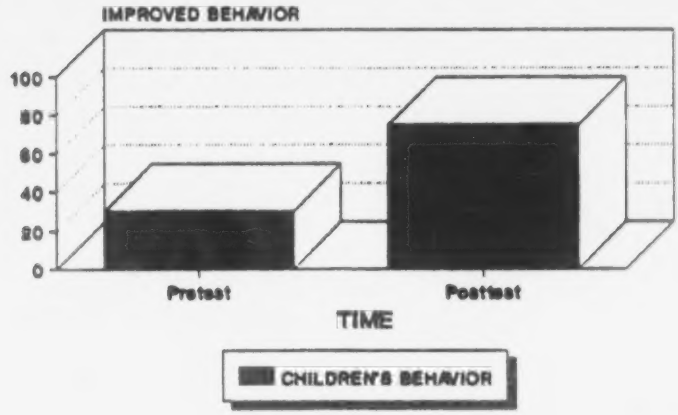
Alpha level:

* "Legendary $p < .05$ "
* Might be relaxed somewhat

QUESTION #5 -- How can I be certain that my intervention caused these changes?

Pre-post a common design:

THEORETICAL RESULTS:
PRETEST-POSTTEST RESEARCH DESIGN



But other possible explanations for this change ("plausible rival hypotheses"):

* History (i.e., other events)
* Maturation (i.e., growth)
* Testing (i.e., familiarity)
* Instrumentation (i.e., change in measuring instrument)
* "Regression to the mean" (i.e., extreme scores tend to revert to average levels)
* Selection (i.e., different populations in different groups)
* "Mortality" (i.e., differential dropout rates)

Designs to reduce these "threats to validity":

* Pre-experimental (bad):
    * Performance monitoring
    * Pretest-posttest (one group)
    * Case studies
    * Cross-sectional surveys
* Quasi-experimental (better):
    * Non-equivalent control groups (possibly with "matching")
    * Longitudinal time series (30+ data points)
* Randomized experiments (best):
    * Pretest-posttest (two or more groups)
    * Post-test only (two or more groups)

<u>QUESTION #6 - How can I ensure that others can learn from my success?</u>

Can the results be generalized:

* To target population
* Across other populations of interest

Sampling plan:

* Multiple populations
* Stratified
* Random sampling

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4. *socio-technological dimensions*—ways in which work should be organized
5. *theories of knowledge* (epistomologies)

The foundations for Kogan's model are selected from the theory of knowledge, social psychology and social policy and illustrate how various assumptions about educational issues can promote different forms of political control, education accountability being a unique and significant case. Professor Kogan has provided us with a comprehensive examination of the issues at hand and does a credible job in broadening the perspective of individuals examining the accountability issue.

Although the context is almost exclusively British, the model has universal relevance for addressing the issue of education accountability and provides the reader with a comprehensive portrait of the interactions of the various elements of the model. Often educators and non-educators tend to focus on one particular aspect of accountability and fail to properly integrate the dimensions of value, affectiveness, sociotechnology and epistomology.

Professor Kogan's work is well written, succinct, and stimulating. The book would be valuable reading for graduate students in education and practicing school administrators, who must face this issue almost daily. The slight inconvenience of adapting the concepts presented to a local framework should not deter scholars from enjoying this analytic overview.

How Many Subjects? Statistical Power Analysis in Research, by Helena Chmura Kraemer and Sue Thiemann, Newbury Park, CA: Sage, 1987, 120 pages.

Reviewer: Charles S. Reichardt

If you want to learn how to do a statistical power analysis with a minimum of effort, this is a book you should read.

As commonly used, the label "statistical power analysis" encompasses two separate, though related, tasks. One task is to determine the level of power that is obtained when a statistical significance test is used with a given sample size. The other task is to determine the sample size needed to obtain a given level of power. As the title of the book suggests, the focus of the volume is on the second task; determining the necessary sample size. In designing a study, this task is usually the more important of the two. Nonetheless, the text allows you to perform the other task as well.

To perform either task, you need to do a few calculations and look up the results in a table. The necessary calculations are explained with the use of clearly labelled formulas and concise examples. Different statistical significance tests require different formulas (and a couple involve calculating an exponential or arcsine). But across the different statistical tests, the formulas are presented using a parallel structure. And most importantly, the formulas are easy to find and decipher, both in the text and in a summary table. As a result, after you have read the text once, months later you will be able to recover the appropriate formulas and figure out how to use them quickly and easily.

After you have performed the relevant calculations, you then look up an answer in a power table. This step is also quick and easy because there is only one table to use and it is laid out in a simple fashion. You use this one table to determine the level of power that is obtained for a given sample size as well as to determine the sample size needed to obtain a given level of power. You also use this one table for all the different statistical tests. Its all very simple.

Of course, statistical power analysis is not completely mechanical. A thoughtful answer requires thoughtful input. For example, to determine the sample size to use in a study, you must decide, among other things, what level of power is adequate and how small a difference between the null and alternative hypotheses you are interested in detecting. But once you make all of these substantive decisions, determining the necessary sample size is purely computational. The beauty of the text by Kraemer and Thiemann is that the computations are made so simple conceptually that you can focus your thinking on the important substantive decisions.

Most of the commonly used statistical tests are covered in the text. Specifically, the text shows how to perform power analyses for tests of means, differences between means, proportions, differences between proportions, correlations, bivariate regression slopes, and variance ratios. For most of these tests, the results of the power calculations are approximations, but there seems to be little need for more exact answers. Often the formulas that are provided allow for useful complexities such as unequal sample sizes, with little loss in conceptual simplicity. The text also presents procedures for assessing power in less commonly used tests such as tests of Spearman's rank correlation and Kendall's tau. These tests are not covered in the classic volume by Cohen (1977), or anywhere else that I know of.

Other statistical significance tests, however, are not considered in the volume. For example, you will have to look elsewhere (e.g., Cohen, 1977) to learn how to do power analyses for tests of coefficients in multiple regression and for tests of differences between correla-

tions. Kraemer and Thiemann do give intuitively appealing procedures for determining power in a balanced analysis of variance and in two-way contingency tables. But the proposed procedures are a bit piecemeal and researchers may wish to supplement them with procedures described in other sources, such as Cohen (1977).

In addition to explaining how to perform power calculations, the text also presents a number of principles for making research cost-effective. For example, the text demonstrates how power is lost by using statistical tests that dichotomize variables measured on a continuous scale. The text also demonstrates the loss in power that results from using unequal sample sizes in tests of mean differences, as well as the increase in power that results from increasing the variability of the independent variables in a regression analysis.

Unfortunately, a couple of the principles that are presented in the text are incorrect. The text incorrectly specifies the conditions under which it would be advantageous to include a pretest measure in a between-group comparison. This is because the text considers the value of adding a pretest only for an analysis of variance on pretest-posttest differences rather than for an analysis of covariance which would be more powerful under most conditions. Indeed, perhaps the most glaring omission in the text's suggestions for cost-effective design is the failure to emphasize the increase in power that can be obtained by adding a covariate. The text also badly misinforms researchers about the value of blocking in analysis of variance. Nonetheless, the virtues of the text outweigh the errors.

Another notable feature of the volume is that it condenses its wealth of information into a remarkably small package. The text of the volume along with accompanying tables takes up only 81 pages. In addition, the pages are small and the type is large. You can read cover to cover in two to three hours. To learn how to do a power analysis for a specific test (e.g., a test of a difference between proportions), you would have to read only two chapters which would take only about half an hour; a small investment to pay for being able to do a power analysis like a pro.

All in all this is a wonderful little book. It makes power analyses quick and easy to perform which means that you'll be more inclined to perform them. Though I think very highly of the volume, I must add one reservation about its use.

If you are going to do statistical significance tests you ought to perform power analyses. But should you use statistical significance tests in the first place? Often, I believe the answer is no. This is because confidence intervals often should be used in place of statistical significance tests. Part of the reason is that statistical significance tests investigate only the direction or existence of a parameter while a confidence interval investigates the size of a parameter, and knowing size usually is preferable (Reichardt & Gollob, 1987).

By explaining simply and clearly how to do power analyses, this book can greatly improve your use of statistical significance tests. For this reason, I hope you buy the book and use it. Although this volume can greatly improve your use of statistical significance tests, your research often could be improved more by using confidence intervals instead.

REFERENCES

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REICHARDT, C.S. & GOLLOB, H.F. (1987). Taking uncertainty into account when estimating effects. In M.M. Mark & R.L. Shotland (Eds.), *Multiple methods for program evaluation* (pp. 7-22). New Directions for Program Evaluation, No. 35. San Francisco: Jossey-Bass.

APPENDIX C

VERMONT SYSTEM FOR TRACKING CLIENT PROGRESS

VERMONT SYSTEM FOR TRACKING CLIENT PROGRESS[1]

INTRODUCTION and PURPOSE

The purpose of this project is to develop a system for tracking client progress through the Vermont System of Care for Children and Adolescents. The information that is collected will be used to improve the provision of services within this System. The clients will be children and adolescents with severely maladjusted behavior who are at risk of being placed in a more restrictive setting.

One way to improve a system of care is to obtain reliable data that relates treatment procedures to treatment outcomes. At the present time, however, there are few service delivery systems that can empirically document behavioral characteristics of the different children that are being served, how the children are being served, and the level of behavior adjustment during and after services. When decisions are made to send a child to an out-of-state residential treatment program, or to wrap individualized services around a child in his or her community it is very unlikely that the decision is based on data that show that the outcome for that treatment is better than that for any other treatment.

There are several ways to defend making treatment decisions in the absence of empirically-based outcome data. It can be argued that 1) different treatments don't make a difference, 2) different treatments do make a difference but we know the difference without outcome data or 3) outcome data may improve our knowledge of the differences but it would not be cost-effective to obtain it. While there is little agreement with the first argument there is considerable support for the other two. With respect to the second, most case-workers/case-managers believe they know whether or not a particular treatment program is effective, at least with respect to the alternatives that are available. They make decisions that are "in the best interest of the child." Nevertheless, it is not uncommon for case-workers/case-managers to disagree amongst themselves. "I use program A because I've had pretty good experiences with it." "She tends to use program B more than I do because she's had better luck with it." The opinions tend to be shaped by experiences with specific children. While personal experience is, and will always be an important part of any treatment decision, the question is whether treatment decisions can be improved with more comprehensive and more objective outcome data. Would it help to know how similar children responded to a range of different treatment programs over a two or three year period? In a few locations in Vermont, intensive, individualized wraparound services are being administered as an alternative to out-of-community residential treatment. Would it help to compare children who receive these very different treatments, both in terms of the nature and severity of maladjusted behavior before treatment as well as with adjustment outcomes after treatment?

---

[1]This client tracking system is based on the work of John VanDenBerg (Alaska Division of Mental Health and Developmental Disabilities), David Born (University of Kansas), and John Burchard and Mark Schaefer (University of Vermont). It is a collaborative effort between the Vermont Departments of Mental Health and Social and Rehabilitation Services, the Vermont Division of Special Education, the Department of Psychology at the University of Vermont, the Alaska Departments of Health and Social Services and Education, and the University of Alaska. Much of this work has been supported by the National Institute of Mental Health (Child and Adolescent Services System Program). The purpose of the copyright is to promote the coordination of any research involving the use of the data collection instruments used in this tracking system.

The Vermont System for Tracking Client Progress (VSTCP) is based on the belief that more comprehensive and more objective client outcome data can result in significant improvements in the existing System of Care. Also with respect to the third concern, it is believed that meaningful and useable outcome data can be obtained without creating an excessive burden in terms of costs and labor. As will be seen below, the most critical and labor-intensive component of VSTCP is obtaining adjustment data on a daily basis. To achieve that objective, it is necessary to identify the most important adjustment indicators and define them in such a way that they can be recorded reliably by a primary caretaker in one to three minutes each day. On the basis of extensive preliminary tests in both Vermont and Alaska, it appears that such an objective can be achieved.

METHODS

Note: The term "residential setting" will be applied to all living situations, whether the child is at home or in some other setting. The term "substitute-care" indicates that the child is living in a setting where the primary caregivers are individuals other than the child's natural parents or relatives.

Subjects

Children and adolescents with severe behavior maladjustment, ranging in age from 3 to 22 years, will be placed on the Vermont System for Tracking Client Progress. It is anticipated that the project will add 50 clients to the tracking system for each of three consecutive years. The client inclusion criteria and the length of time clients will be in the project will be determined by a Project Advisory Committee that is being established with representation from relevant state agencies, providers, advocates, and consumers.

Measures

The VSTCP is comprised of four components, the Daily Adjustment Component (DAC), the Bi-annual Adjustment Component (BAC), the Service Tracking Component (STC), and the Consumer Satisfaction Component (CSC). Each component will be described separately.

Daily Adjustment Component (DAC)

The DAC consists of a behavior checklist of adjustment indicators which is designed to measure those behaviors which place a child at risk of placement into a more restrictive setting. It is a daily checklist which requires the respondent to record on an optical scanner form whether a behavior did or did not occur. The checklist measures occurrence or non-occurrence as opposed to the frequency of occurrence. A backup respondent will be designated in the event that the primary respondent is unavailable. Social validity and inter-rater reliability are currently being assessed. Completion of the DAC should not require more than 1-3 minutes per child. It is intended to be used wherever the child resides, whether in the home or in a substitute-care setting. See Appendix A for a list of each of the adjustment indicators and definitions. A training manual is currently being developed to help respondents learn critical components of each definition.

Bi-annual Adjustment Component (BAC)

The BAC is composed of the parent (CBCL), teacher (TRF), and youth (YSR) behavior checklists designed by Tom Achenbach and Craig Edelbrock. The CBCL will be administered to parents or residential staff every six months. The TRF will be administered to educational staff and the YSR will be administered to youth 11 years of

age or older. They each relate to the childs' adjustment over a preceding 6 month period of time and focus on both social competence and problem behaviors. These measures have excellent reliability and validity. All of these checklists require approximately 15 minutes to complete.

Service Tracking Component (STC)
The Service Tracking Component will be designed to provide weekly information regarding the provision of services to a child. It is of interest to determine where services are being provided and the nature and frequency of those services. Records will be kept of changes in residential or educational setting, and significant service delivery changes within either of those settings. This form is currently in development.

Consumer Satisfaction Component (CSC)
The Consumer Satisfaction Component (CSC) is comprised of Consumer Satisfaction Questionnaires that are being designed for parents, children, and adolescents. The child's parent(s) or legal guardian will fill out a Consumer Satisfaction Questionnaire every six months. Children and adolescents who have given their assent will also be given a Consumer Satisfaction Questionnaire bi-annually. It is anticipated that these questionnaires will require approximately 15-30 minutes to complete.

Consent

Informed consent to place the child on the tracking system will be obtained from the child's parent or the Commissioner of SRS if the child is in the custody of the State. Informed consent will also be obtained from each individual respondent with respect to their participation. In those cases where staff rotation would preclude the designation of a single respondent, consent will be obtained from the program director.

Those portions of the system for which the child or youth is asked to be the respondent (ie. the YSR and Child or Youth Consumer Satisfaction Questionnaire) will require their assent provided they are 11 years of age or older. For those children who do not wish to participate, data will be collected from adult respondents only.

Timeline

The Daily Adjustment Component of the tracking system is presently being field tested on a small number of clients who are receiving services within different components of the Vermont System of Care. In addition data relating to social validity and reliability is currently being collected. Undergraduate students will implement the system and are currently taking part in an extensive training process. It is anticipated that all components of the tracking system will in place by late February.

Any questions regarding this project should be addressed to either John Burchard or Mark Schaefer in the Psychology Department at the University of Vermont. Phone: (802) 656-2670.

DAILY ADJUSTMENT INDICATORS

ID# _____

Week beginning _____ (MONTH/DAY/YEAR)

Directions: *Please indicate according to your best judgement whether or not the following behaviors or events have occurred on this day. Fill in the appropriate circle.* (Y=YES, N=NO)

	M	T	W	T	F	S	S
1. **PHYSICAL AGGRESSION:** Did the child or youth hit, strike, bite, or scratch a person with intent to harm them? (Includes hitting with an object.)	Y N	Y N	Y N	Y N	Y N	Y N	Y N
2. **PROPERTY DAMAGE:** Did the child or youth damage property on purpose?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
3. **THEFT:** Did the child or youth take property without permission?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
4. **RUNAWAY:** Did the child or youth run away?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
5. **ALCOHOL/DRUG USE:** Did the child or youth use drugs or alcohol without permission?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
6. **SEXUAL ACTING OUT:** Did the child or youth engage in inappropriate sexual behavior which was displayed publicly or directed toward another person?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
7. **EXTREME VERBAL ABUSE:** Did the child or youth speak to another person in an extremely malicious, abusive or intimidating manner?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
8. **SAD:** Was the child or youth sad, withdrawn, or depressed to a degree which significantly interfered with participation in an important activity?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
9. **ANXIOUS:** Was the child or youth fearful, anxious, or worried to a degree which significantly interfered with participation in an important activity?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
10. **SELF-INJURY:** Did the child or youth harm or attempt to harm him or herself nonaccidentally?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
11. **INAPPROPRIATE BOWEL MOVEMENTS:** Did the child or youth intentionally smear his or her feces or deposit them in an inappropriate place?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
12. **LIFE THREAT:** Did the child or youth threaten or engage in physical assault in a manner which which you believe was life threatening?	Y N	Y N	Y N	Y N	Y N	Y N	Y N
13. **SEXUAL ABUSE/ASSAULT:** Did the child or youth attempt to force him or herself upon another person sexually?	Y N	Y N	Y N	Y N	Y N	Y N	Y N

DAILY ADJUSTMENT INDICATORS, SIDE 2

	M	T	W	T	F	S	S
14. **SUICIDE ATTEMPT:** Did the child or youth attempt to commit suicide?	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ
15. **FIRESETTING:** Did the child or youth set a fire without permission or set a fire in a manner which could have resulted in property damage or harm to others?	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ
16. **STRANGE BEHAVIOR:** Did the youth have delusions, hallucinations, obsessions, compulsions, or other bizarre behavior which significantly interfered with an important activity?	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ
17. **CRUELTY TO ANIMALS:** Did the child or youth torture, kill, or behave very cruelly toward any animal on purpose? (Does not include hunting with permission.)	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ
18. **SELF-CONFIDENCE:** Did the child or youth appear self-confident in his or her activities for more than 85% of the time?	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ
19. **COMPLIANCE:** Was the child's or youth's response to requests and general activity acceptable 85% of the time?	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ
20. **PEER INTERACTIONS:** Did the child or youth have good peer/sibling relations 85% of the time? (Please check ☐ if no peer or sibling contact on this day.)	ⓨⓝ ☐	ⓨⓝ ☐	ⓨⓝ ☐	ⓨⓝ ☐	ⓨⓝ ☐	ⓨⓝ ☐	ⓨⓝ ☐
21. **SCHOOL ATTENDANCE:** As far as you know, did the child or youth receive credit for school attendance? (Please check ☐ if there was no school today.)	ⓨⓝ ☐	ⓨⓝ ☐	ⓨⓝ ☐	ⓨⓝ ☐	ⓨⓝ ☐	ⓨⓝ ☐	ⓨⓝ ☐
22. **PARENT CONTACT:** Did the child or youth have contact with his or her natural or adoptive parent(s) on this day? (Includes letter, telephone call, or personal visit.)	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ
23. **VOCATIONAL INVOLVEMENT:** Did the child or youth work for pay (check "P") or as a volunteer (check "V")? (If the child or youth did not work check ☐)	ⓅⓋ ☐	ⓅⓋ ☐	ⓅⓋ ☐	ⓅⓋ ☐	ⓅⓋ ☐	ⓅⓋ ☐	ⓅⓋ ☐
24. **POLICE CONTACT:** Did the child or youth have contact with the police concerning his or her negative or suspicious behavior?	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ	ⓨⓝ

25. **POSITIVE:** What did the child or youth do today that was good?

Monday _____

Tuesday _____

Wednesday _____

Thursday _____

Friday _____

Saturday _____

Sunday _____

GENERAL COMMENTS: _____

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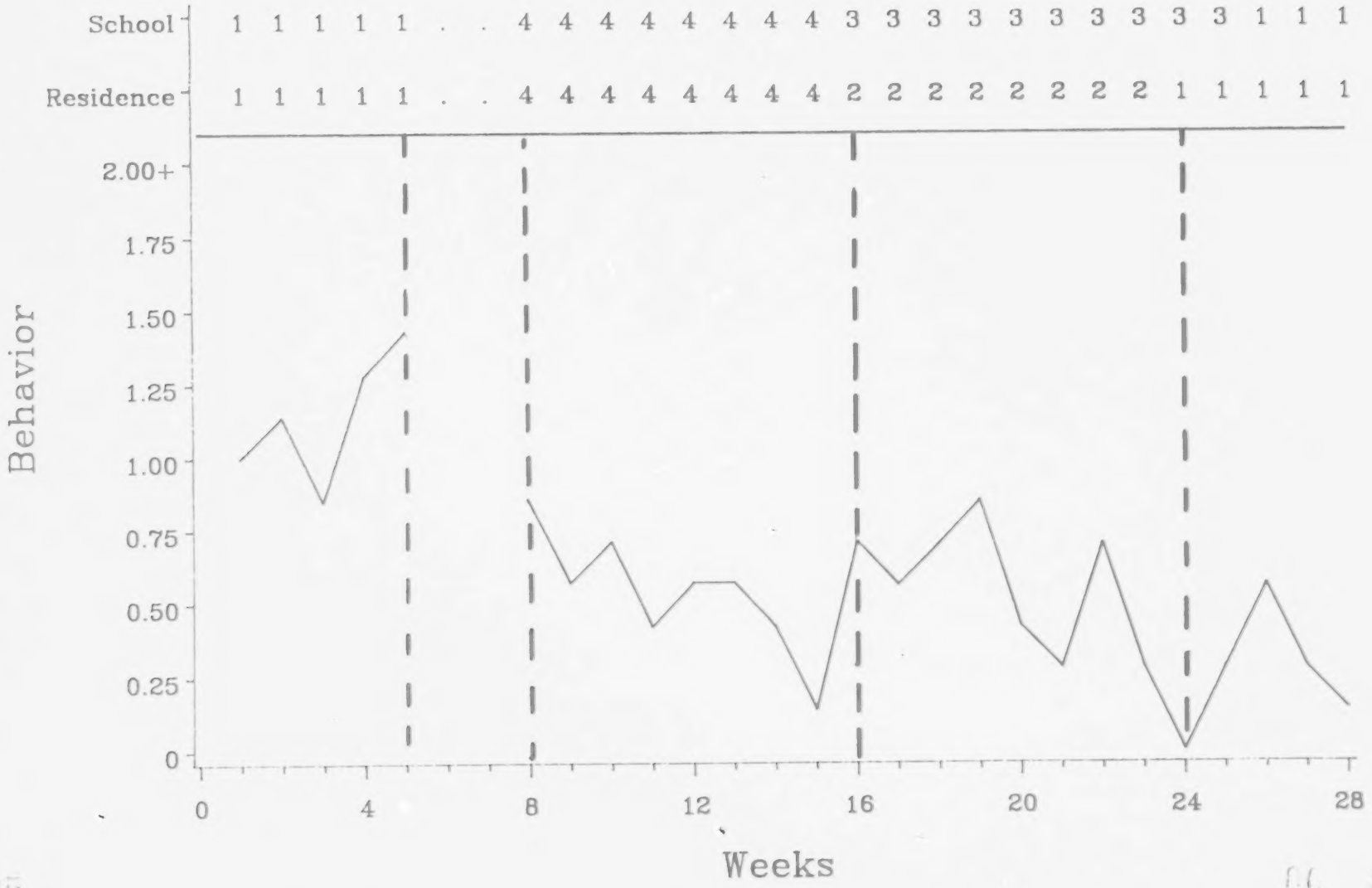
M-12

Behavior Adjustment Component



APPENDIX D

SOME POSSIBLE MEASURES FOR IMPROVEMENTS TO THE CASSP SYSTEM AND SERVICE DELIVERY

SOME POSSIBLE MEASURES OF IMPROVEMENTS

TO THE CASSP SYSTEM AND TO ITS SERVICE DELIVERY

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Presented at:

CASSP Technical Assistance Research Meeting
Georgetown University
Washington, DC

May 2, 1990

DRAFT

SIX (UNOFFICIAL) GOALS OF CASSP

#1: Increase the visibility and priority of children's mental health services

#2: Increase funding for children's mental health services across the continuum of care

#3: Serve more children as appropriately as possible

#4: Improve the efficiency of service delivery among different child-serving agencies

#5: Involve families in planning and treatment efforts

#6: Assure that services are provided in a culturally sensitive manner

DRAFT

GOAL #1: INCREASE THE VISIBILITY AND PRIORITY OF CHILDREN'S MENTAL HEALTH SERVICES

System Improvements:

* Establish a focal point for children's mental health services
* Develop top-level support for children's mental health services
* Develop public support for children's mental health services
* Develop a planning process that involves all key players
* Define the target population
* Complete a needs assessment of the target population
* Develop a children's mental health plan
* Include children and adolescents as a priority population in mental health plans or other official documents
*
*

Service Delivery Improvements:

* Identify all needy children in the target population
*
*

DRAFT

GOAL #2: INCREASE FUNDING FOR CHILDREN'S MENTAL HEALTH SERVICES ACROSS THE CONTINUUM OF CARE

System Improvements:

* Increase the overall resources available for children's mental health services

* Expand Medicaid reimbursement for needed services

* Access new funds from private sources

* Increase the proportion of total mental health funds earmarked for children's services

*

*

Service Delivery Improvements:

* Increase the proportion of identified target population served

*

*

DRAFT

GOAL #3: SERVE MORE CHILDREN AS APPROPRIATELY AS POSSIBLE

System Improvements:

* Modify legislation, regulations, policies, standards, etc. as needed to develop a full range of services
* Reallocate resources, especially from out-of-state and institutional-based services to in-state and community-based services
* Support mini-demonstrations of components of continuum of care
* Stimulate the supply of trained professionals
*
*

Service Delivery Improvements:

* Increase the number of slots available in each core service
* Decrease the total number, relative proportion, and length of restrictive placements (e.g., out-of-state, out-of-home, institutional)
* Increase the utilization of alternatives to hospitals and residential treatment centers
*
*

DRAFT

GOAL #4: IMPROVE THE EFFICIENCY OF SERVICE DELIVERY AMONG DIFFERENT CHILD-SERVING AGENCIES

System Improvements:

* Establish formal coordination mechanisms (committees, task forces, etc.)
* Establish formal interagency agreements
* Develop joint funding initiatives
* Develop joint programming initiatives
* Develop joint case-management policies and procedures
*
*

Service Delivery Improvements:

* Increase the total number and relative proportion of children with case managers
* Establish an individual treatment plan for each child
*
*

DRAFT

GOAL #5: INVOLVE FAMILIES IN PLANNING AND TREATMENT EFFORTS

System Improvements:

* Develop new family support and/or advocacy groups (e.g., sponsor conferences or workshops, train family members, provide information)

* Include families on key policymaking, planning, and advisory groups

* Involve families in developing the State plan and other planning efforts

*

*

Service Delivery Improvements:

* Involve each child's family in treatment planning and service delivery

*

*

DRAFT

GOAL #6: ASSURE THAT SERVICES ARE PROVIDED IN A CULTURALLY SENSITIVE MANNER

System Improvements:

* Include minorities on key policymaking, planning, and advisory groups
* Involve minorities in developing the State plan and other planning efforts
* Conduct a special assessment of minority needs
* Develop special plans for providing culturally sensitive services
* Train staff regarding cultural sensitivity
* Sponsor conferences, workshops, forums, etc. on cultural sensitivity
*
*

Service Delivery Improvements:

* Hire bilingual and/or bicultural staff
* Develop specialized programs or services for minority populations
*
*

APPENDIX E

PROTECTION OF HUMAN SUBJECTS

OPRR Reports

NIH PHS HHS

PROTECTION OF HUMAN SUBJECTS

CODE OF FEDERAL REGULATIONS

45 CFR 46

Revised as of March 8, 1983

NATIONAL RESEARCH ACT
PUBLIC LAW 93–348
JULY 12, 1974

INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

SEC. 212. (a) Part I of title IV of the Public Health Service Act, as amended by section 103 of this Act, is amended by adding at the end the following new section:

"INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

"SEC. 474. (a) The Secretary shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant or contract assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an 'Institutional Review Board') to review biomedical and behavioral research involving human subjects conducted at or sponsored by such entity in order to protect the rights of the human subjects of such research.

"(b) The Secretary shall establish a program within the Department under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately."

(b) The Secretary of Health, Education, and Welfare shall within 240 days of the date of the enactment of this Act promulgate such regulations as may be required to carry out section 474(a) of the Public Health Service Act. Such regulations shall apply with respect to applications for grants and contracts under such Act submitted after promulgation of such regulations.

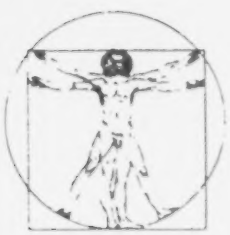
THE CODE OF FEDERAL REGULATIONS,
45 CFR 46, IMPLEMENTS THESE AMENDMENTS
TO THE PUBLIC HEALTH SERVICE ACT.

salus ubi multi consiliarii

CODE OF FEDERAL REGULATIONS

TITLE 45
PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
OFFICE FOR PROTECTION FROM RESEARCH RISKS



PART 46—PROTECTION OF HUMAN SUBJECTS
REVISED AS OF MARCH 8, 1983

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Sec.
46.101 To what do these regulations apply?
46.102 Definitions.
46.103 Assurances.
46.104 Section reserved.
46.105 Section reserved.
46.106 Section reserved.
46.107 IRB membership.
46.108 IRB functions and operations.
46.109 IRB review of research.
46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
46.111 Criteria for IRB approval of research.
46.112 Review by institution.
46.113 Suspension or termination of IRB approval of research.
46.114 Cooperative research.
46.115 IRB records.
46.116 General requirements for informed consent.
46.117 Documentation of informed consent.
46.118 Applications and proposals lacking definite plans for involvement of human subjects.
46.119 Research undertaken without the intention of involving human subjects.
46.120 Evaluation and disposition of applications and proposals.
46.121 Investigational new drug or device 30-day delay requirement.
46.122 Use of federal funds.
46.123 Early termination of research funding; evaluation of subsequent applications and proposals.
46.124 Conditions.

Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Sec.
46.201 Applicability.
46.202 Purpose.
46.203 Definitions.
46.204 Ethical Advisory Boards.
46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.
46.206 General limitations.
46.207 Activities directed toward pregnant women as subjects.
46.208 Activities directed toward fetuses in utero as subjects.
46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.
46.210 Activities involving the dead fetus, fetal material, or the placenta.
46.211 Modification or waiver of specific requirements.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Sec.
46.301 Applicability.
46.302 Purpose.
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46.304 Composition of Institutional Review Boards where prisoners are involved.
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Subpart D—Additional Protections for Children Involved as Subjects in Research

Sec.
46.401 To what do these regulations apply?
46.402 Definitions.
46.403 IRB duties.
46.404 Research not involving greater than minimal risk.
46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
46.408 Requirements for permission by parents or guardians and for assent by children.
46.409 Wards.

Authority: 5 U.S.C. 301; sec. 474(a), 88 Stat. 352 (42 U.S.C. 289*l*-3(a)).

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Source: 46 FR 8386, January 26, 1981, 48 FR 9269, March 4, 1983.

§ 46.101 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving human subjects conducted by the Department of Health and Human Services or funded in whole or in part by a Department grant, contract, cooperative agreement or fellowship.

(1) This includes research conducted by Department employees, except each Principal Operating Component head may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or funded by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of this section waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from these regulations unless the research is covered by other subparts of this part:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if

information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(3) Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

(4) Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(5) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(6) Unless specifically required by statute (and except to the extent specified in paragraph (i)), research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(c) The Secretary has final authority to determine whether a particular activity is covered by these regulations.

(d) The Secretary may require that specific research activities or classes of research activities conducted or funded by the Department, but not otherwise covered by these regulations, comply with some or all of these regulations.

(e) The Secretary may also waive applicability of these regulations to specific research activities or classes of research activities, otherwise covered by these regulations. Notices of these actions will be published in the *Federal Register* as they occur.

(f) No individual may receive Department funding for research covered by these regulations unless the individual is affiliated with or sponsored by an institution which assumes responsibility for the research under an assurance satisfying the requirements of this part, or the individual makes other arrangements with the Department.

(g) Compliance with these regulations will in no way render inapplicable pertinent federal, state, or local laws or regulations.

(h) Each subpart of these regulations contains a separate section describing to what the subpart applies. Research which is covered by more than one subpart shall comply with all applicable subparts.

(i) If, following review of proposed research activities that are exempt from these regulations under paragraph (b)(6), the Secretary determines that a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a participant or subject of the research or demonstration project, then federal funds may not be expended for such a project without the written, informed consent of each participant or subject.

§ 46.102 Definitions.

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "Department" or "HHS" means the Department of Health and Human Services.

(c) "Institution" means any public or private entity or agency (including federal, state, and other agencies).

(d) "Legally authorized representative" means an indivldual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(e) "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of these regulations, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

(f) "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(h) "Certification" means the official notification by the institution to the Department in accordance with the requirements of this part that a research project or activity involving human subjects has been reviewed and approved by the Institutional Review Board (IRB) in accordance with the approved assurance on file at HHS. (Certification is required when the research is funded by the Department and not otherwise exempt in accordance with § 46.101(b)).

§ 46.103 Assurances.

(a) Each institution engaged in research covered by these regulations shall provide written assurance satisfactory to the Secretary that it will comply with the requirements set forth in these regulations.

(b) The Department will conduct or fund research covered by these regulations only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the Secretary that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. This assurance shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of source of funding. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of these regulations applicable to Department-funded research and is not applicable to any research in an exempt category listed in § 46.101.

(2) Designation of one or more IRBs established in accordance with the requirements of this subpart, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Secretary.[1]

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; (iii) for insuring prompt reporting to the IRB of proposed changes in a research activity, and for insuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subject; and (iv) for insuring prompt reporting to the IRB and to the Secretary[1] of unanticipated problems involving risks to subjects or others.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by these regulations, and shall be filed in such form and manner as the Secretary may prescribe.

(d) The Secretary will evaluate all assurances submitted in accordance with these regulations through such officers and employees of the Department and such experts or consultants engaged for this purpose as the Secretary determines to be appropriate. The Secretary's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the Secretary may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The Secretary may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Within 60 days after the date of submission to HHS of an application or proposal, an institution with an approved assurance covering the proposed research shall certify that the application or proposal has been reviewed and approved by the IRB. Other institutions shall certify that the application or proposal has been approved by the IRB within 30 days after receipt of a request for such a certification from the Department. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

§ 46.104 [Reserved]

§ 46.105 [Reserved]

§ 46.106 [Reserved]

§ 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, including but not limited to subjects covered by other subparts of this part, the IRB shall include one or more individuals who are primarily concerned with the welfare of these subjects.

(b) No IRB may consist entirely of men or entirely of women, or entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in nonscientific areas; for example: lawyers, ethicists, members of the clergy.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.

In order to fulfill the requirements of these regulations each IRB shall:

(a) Follow written procedures as provided in § 46.103(b)(4).

(b) Except when an expedited review procedure is used (see § 46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

(c) Be responsible for reporting to the appropriate institutional officials and the Secretary[1] any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.

§ 46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned in § 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary has established, and published in the *Federal Register*, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication in the *Federal Register*.

(b) An IRB may review some or all of the research appearing on the list through an expedited review procedure, if the research involves no more than minimal risk. The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Secretary may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects.

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.

Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Secretary.[1]

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

§ 46.114 Cooperative research.

Cooperative research projects are those projects, normally supported through grants, contracts, or similar arrangements, which involve institutions in addition to the grantee or prime contractor (such as a contractor with the grantee, or a subcontractor with the prime contractor). In such instances, the grantee or prime contractor remains responsible to the Department for safeguarding the rights and welfare of human subjects. Also, when cooperating institutions conduct some or all of the research involving some or all of these subjects, each cooperating institution shall comply with these regulations as though it received funds for its participation in the project directly from the Department, except that in complying with these regulations institutions may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

§ 46.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members as required by § 46.103(b)(3).

(6) Written procedures for the IRB as required by § 46.103(b)(4).

(7) Statements of significant new findings provided to subjects, as required by § 46.116(b)(5).

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department at reasonable times and in a reasonable manner.

§ 46.116 General requirements for informed consent.

Except as provided elsewhere in this or other subparts, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in these regulations are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A "short form" written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to the Department with the knowledge that subjects may be involved within the

period of funding, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants (including bloc grants) where selection of specific projects is the institution's responsibility; research training grants where the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research described in § 46.101(b), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in these regulations, and certification submitted to the Department.

§ 46.119 Research undertaken without the intention of involving human subjects.

In the event research (conducted or funded by the Department) is undertaken without the intention of involving human subjects, but it is later proposed to use human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in these regulations, a certification submitted to the Department, and final approval given to the proposed change by the Department.

§ 46.120 Evaluation and disposition of applications and proposals.

(a) The Secretary will evaluate all applications and proposals involving human subjects submitted to the Department through such officers and employees of the Department and such experts and consultants as the Secretary determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

(b) On the basis of this evaluation, the Secretary may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 46.121 Investigational new drug or device 30-day delay requirement.

When an institution is required to prepare or to submit a certification with an application or proposal under these regulations, and the application or proposal involves an investigational new drug (within the meaning of 21 U.S.C. 355(i) or 357(d)) or a significant risk device (as defined in 21 CFR 812.3(m)), the institution shall identify the drug or device in the certification. The institution shall also state whether the 30-day interval required for investigational new drugs by 21 CFR 312.1(a) and for significant risk devices by 21 CFR 812.30 has elapsed, or whether the Food and Drug Administration has waived that requirement. If the 30-day interval has expired, the institution shall state whether the Food and Drug Administration has requested that the sponsor continue to withhold or restrict the use of the drug or device in human subjects. If the 30-day interval has not expired, and a waiver has not been received, the institution shall send a statement to the Department upon expiration of the interval. The Department will not consider a certification acceptable until the institution has submitted a statement that the 30-day interval has elapsed, and the Food and Drug Administration has not requested it to limit the use of the drug or device, or that the Food and Drug Administration has waived the 30-day interval.

§ 46.122 Use of Federal funds.

Federal funds administered by the Department may not be expended for research involving human subjects unless the requirement of these regulations, including all subparts of these regulations, have been satisfied.

§ 46.123 Early termination of research funding; evaluation of subsequent applications and proposals.

(a) The Secretary may require that Department funding for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the Secretary finds an institution has materially failed to comply with the terms of these regulations.

(b) In making decisions about funding applications or proposals covered by these regulations the Secretary may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person who would direct the scientific and technical aspects of an activity has in the judgment of the Secretary materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not Department funds were involved).

§ 46.124 Conditions.

With respect to any research project or any class of research projects the Secretary may impose additional conditions prior to or at the time of funding when in the Secretary's judgment additional conditions are necessary for the protection of human subjects.

Subpart B—Additional Protections Pertaining to Research Development, and Related Activities Involving Fetuses, Pregnant Women, and Human in Vitro Fertilization

SOURCE: 40 FR 33528, Aug. 8, 1975, 43 FR 1758, January 11, 1978, 43 FR 51559, November 3, 1978

§ 46.201 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare

grants and contract supporting research, development, and related activities involving: (1) The fetus, (2) pregnant women, and (3) human *in vitro* fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

§ 46.203 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following explusion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.

(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.

(f) "Dead fetus" means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

(g) "*In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

§ 46.204 Ethical Advisory Boards.

(a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these board(s) shall be so selected that the board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No board member may be a regular, full-time employee of the Department of Health, Education, and Welfare.

(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the policies and requirements of this Part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) Must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

(d) No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

§ 46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.

(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part, the applicant's or offeror's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) Determine that all aspects of the activity meet the requirements of this subpart;

(2) Determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) Overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or

verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);

(3) Carry out such other responsibilities as may be assigned by the Secretary.

(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in § 46.120 of Subpart A of this part.

(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.

§ 46.206 General limitations.

(a) No activity to which this subpart is applicable may be undertaken unless:

(1) Appropriate studies on animals and nonpregnant individuals have been completed;

(2) Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity.

(3) Individuals engaged in the activity will have no part in: (i) Any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

[40 FR 33528, Aug. 8, 1975, as amended at 40 FR 51638, Nov. 6, 1975]

§ 46.207 Activities directed toward pregnant women as subjects.

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) The purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

§ 46.208 Activities directed toward fetuses in utero as subjects.

(a) No fetus *in utero* may be involved as a subject in any activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) His identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.

(a) Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity covered by this subpart unless:

(1) There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

(2) The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:

(1) Vital functions of the fetus will not be artificially maintained,

(2) Experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

(3) The purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(c) In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is

not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.210 Activities involving the dead fetus, fetal material, or the placenta.

Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

§ 46.211 Modification or waiver of specific requirements.

Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the FEDERAL REGISTER.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Source: 43 FR 53655, Nov 16, 1978

§ 46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health, Education, and Welfare involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§ 46.303 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "DHEW" means the Department of Health, Education, and Welfare.

(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§ 46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in § 46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

§ 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under § 46.306(a)(2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to

all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHEW may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(A) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(B) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(C) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(D) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHEW shall not involve prisoners as subjects.

Subpart D—Additional Protections for Children Involved as Subjects in Research.

Source: 48 FR 9818, March 8, 1983

§ 46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of § 46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions (1), (2), (5) and (6) as listed in Subpart A at § 46.101(b) are applicable to this subpart. Exemption (4), research involving the observation of public behavior, listed at § 46.101(b), is applicable to this subpart where the investigator(s) does not participate in the activities being observed. Exemption (3), research involving survey or interview procedures, listed at § 46.101(b) does not apply to research covered by this subpart.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of § 46.101 of Subpart A are applicable to this subpart.

§ 46.402 Definitions.

The definitions in § 46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) "Parent" means a child's biological or adoptive parent.

(e) "Guardian" means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

§ 46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§ 46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of §§ 46.404, 46.405, or 46.406 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: (1) That the research in fact satisfies the conditions of §§ 46.404, 46.405, or 46.406, as applicable, or (2) the following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles;

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment

may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §§ 46.404 or 46.405. Where research is covered by §§ 46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§ 46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §§ 46.406 or 46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

NOTICES

HUMAN SUBJECTS
Minimum Criteria Identifying the Viable Fetus

On March 13, 1975, regulations were published in the FEDERAL REGISTER (40 FR 11854) relating to the protection of human subjects in research, development, and related activities supported by Department of Health, Education, and Welfare grants and contracts. These regulations are codified at 45 CFR Part 46.

Elsewhere in this issue of the FEDERAL REGISTER, the Secretary is amending 45 CFR Part 46 by, among other things, adding a new Subpart B to provide additional protections pertaining to research, development, and related activities involving fetuses, pregnant women, and in vitro fertilization.

Section 46.203(d) of Subpart B provides inter alia as follows:

> The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a fetus is viable for purposes of this subpart.

This notice is published in accordance with § 46.203(d). For purposes of Subpart B, the guidelines indicating that a fetus other than a dead fetus within the meaning of § 46.203(f) is viable include the following:

> an estimated gestational age of 20 weeks or more and a body weight of 500 grams or more.

FEDERAL REGISTER, VOL 40, AUGUST 8, 1975

RESEARCH ACTIVITIES WHICH MAY BE REVIEWED THROUGH EXPEDITED REVIEW PROCEDURES

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the Institutional Review Board through the expedited review procedure authorized in 46.110 of 45 CFR Part 46.

(1) Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

(2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

(3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

(5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(6) Voice recordings made for research purposes such as investigations of speech defects.

(7) Moderate exercise by healthy volunteers.

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

(10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

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APPENDIX F

TECHNICAL ASSISTANCE RESOURCES

TECHNICAL ASSISTANCE RESOURCES

Child and Adolescent Service System Program (CASSP)
Child and Family Support Branch
Division of Applied and Services Research
Room 11 C-09
5600 Fishers Lane
Rockville, MD 20857
(301) 443-1333

CASSP Technical Assistance Center
Georgetown University Child Development Center
2233 Wisconsin Avenue, N.W.
Washington, D.C. 20007
(202) 338-1831

Research and Training Center for
Children's Mental Health
Florida Mental Health Institute
University of South Florida
13301 Bruce B. Downs Blvd.
Tampa, FL 33612-3899
(813) 974-4500

Research and Training Center on
Family Support and Children's Mental Health
Portland State University
P.O. Box 751
Portland, OR 97207-0751
(503) 725-4040